

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 - - -

5
6 IN RE: NATIONAL : HON. DAN A.
7 PRESCRIPTION OPIATE : POLSTER
8 LITIGATION :
9 : MDL NO. 2804
10 APPLIES TO ALL CASES :
11 : CASE NO.
12 : 17-MD-2804
13 :

14 - HIGHLY CONFIDENTIAL -
15 SUBJECT TO FURTHER CONFIDENTIALITY REVIEW
16 VOLUME II

17 - - -

18 May 17, 2019

19 - - -

20 Continued videotaped
21 deposition of DR. SETH B. WHITELOW, taken
22 pursuant to notice, was held at the
23 offices of Golkow Litigation Services,
24 One Liberty Place, 1650 Market Street,
25 Philadelphia, Pennsylvania, beginning at
26 8:31 a.m., on the above date, before
27 Michelle L. Gray, a Registered
28 Professional Reporter, Certified
29 Shorthand Reporter, Certified Realtime
30 Reporter, and Notary Public.

31 - - -

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I N D E X

Testimony of:

DR. SETH B. WHITELAW

By Ms. Wicht	539
By Mr. Melton	645
By Mr. Hynes	707
By Mr. Davison	821
By Mr. Bogle	992

E X H I B I T S

NO.	DESCRIPTION	PAGE
Whitelaw-14	Hearing Before the US House of Reps Committee on Energy 5/8/18 (Barrett)	578
Whitelaw-15	Excerpt of Transcript Of Steve Reardon 11/30/18	587
Whitelaw-16	Excerpt of Transcript Of William De Gutierrez Mahoney, 11/28/18	589
Whitelaw-17	Settlement & Release Agreement ABDCMDL00279854-65	675

1		- - -	
2		E X H I B I T S (Cont'd.)	
3		- - -	
4			
5	NO.	DESCRIPTION	PAGE
6	Whitelaw-18	E-mail Thread 1/18/11 Subject, Control IRR Dated 1/18/11 CVS-MDLT1-000101073	769
7			
8			
9	Whitelaw-19	E-mail Thread 2/7/14 Subject, Control/PSE IRR CVS-MDLT1-000008496-99	801
10			
11			
12	Whitelaw-20	E-mail Thread 12/10/13 Subject, Control/PSE IRR CVS_MDLT1-000008483-87	805
13			
14			
15	Whitelaw-21	Appendix I: List of Materials Considered	822
16			
17	Whitelaw-22	E-mail Thread 12/1/10 Subject, Additional Feedback from Albany DEA on Mallinckrodt's SOM Activities MNK-T1_0000372132	868
18			
19			
20			
21	Whitelaw-23	Distinct Mallinckrodt Documents Considered By Seth Whitelaw, Per Year (Demonstrative)	927
22			
23			
24			

1		- - -	
2		E X H I B I T S (Cont'd.)	
3		- - -	
4			
5	NO.	DESCRIPTION	PAGE
6	Whitelaw-24	Mallinckrodt	951
7		Handwritten	
8		Notes, by Dr.	
9		Whitelaw	
10	Whitelaw-25	E-mail Thread,	952
11		11/14/11	
12		Subject, Mallinckrodt	
13		Suspicious Order	
14		Monitoring	
15		MNK-T1_0007711276-81	
16	Whitelaw-26	Notes from Meeting	956
17		At DEA St. Louis Office	
18		11/1/10	
19		MNK-T1_0000421974-75	
20	Whitelaw-27	Letter, 12/20/07	989
21		From Rannazzisi	
22			
23			
24			

1 - - -

2 DEPOSITION SUPPORT INDEX

3 - - -

4

5 Direction to Witness Not to Answer

6 PAGE LINE

None.

7

8 Request for Production of Documents

9 PAGE LINE

None.

10

11 Stipulations

12 PAGE LINE

None.

13

14 Questions Marked

15 PAGE LINE

None.

16

17

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THE VIDEOGRAPHER: Back on

3

the record.

4

My name is David Lane,

5

videographer for Golkow Litigation

6

Services.

7

Today's date is May 17,

8

2019, and our time is 8:31 a.m.

9

This deposition is taking

10

place in Philadelphia,

11

Pennsylvania, in the matter of

12

National Prescription Opiate

13

Litigation MDL.

14

Our deponent today is

15

Dr. Seth Whitelaw.

16

Our counsel will be noted on

17

the stenographic record.

18

The court reporter today is

19

Michelle Gray.

20

Dr. Whitelaw, I just want to

21

remind you, you're still under

22

oath from yesterday.

23

THE WITNESS: I understand.

24

1 questions this morning.

2 A. Good morning, Jennifer.

3 Q. It's nice to meet you. So I
4 want to start, Dr. Whitelaw, by asking
5 you a couple of questions to make sure
6 that I understand the scope of your
7 opinions that you're offering about
8 Cardinal Health in your reports. Okay?

9 A. Okay.

10 Q. So first of all,
11 Dr. Whitelaw, you are not offering any
12 opinions about any specific methodology
13 that Cardinal Health -- you believe
14 Cardinal Health should have used to
15 identify suspicious orders, correct?

16 MR. BOGLE: Object to form.

17 THE WITNESS: Could you be a
18 little more specific with that?

19 Because I'm not sure where you --
20 what you mean by methodology.

21 BY MS. WICHT:

22 Q. Do you understand that there
23 are a variety of different ways that a
24 registrant could identify suspicious

1 orders by -- placed by their customers?

2 A. Are we talking about
3 thresholds? Are we talking about
4 systems? Again, methodology is a very
5 broad term in the world that I work in.
6 I need you to be -- I'm not trying to be
7 difficult. Could you be a little more
8 precise.

9 Q. Sure. For example, a
10 registrant could use a methodology like
11 thresholds. A registrant could use a
12 methodology that tracked growth over
13 time. A registrant could use a variety
14 of different calculations or
15 methodologies in order to try to identify
16 suspicious orders, correct?

17 A. That is correct.

18 Q. And you are not offering an
19 opinion as to what particular methodology
20 or any particular methodology Cardinal
21 Health should have used --

22 A. No, I'm not --

23 Q. -- to identify suspicious
24 orders?

1 A. -- offering an opinion--

2 MR. BOGLE: Just let her
3 finish.

4 THE WITNESS: Sorry.

5 -- on a particular
6 methodology as the way that you've
7 just defined it.

8 BY MS. WICHT:

9 Q. Thank you. And you're not
10 offering any opinions about any
11 particular orders that were placed with
12 Cardinal Health that you believe in your
13 opinions were suspicious and not reported
14 to DEA, correct?

15 MR. BOGLE: Object to form.

16 THE WITNESS: Again, I think
17 we need to narrow what you're
18 asking, because I'm not sure. You
19 are asking a very broad question.
20 Can we narrow it?

21 BY MS. WICHT:

22 Q. Have you identified -- do
23 you have -- have you identified any
24 specific order placed by a customer to

1 Cardinal Health that you opine is
2 suspicious and should have been reported
3 to DEA but was not?

4 MR. BOGLE: Object to form.

5 THE WITNESS: Again, as I
6 mentioned yesterday, and I'll
7 reiterate for you today. I am a
8 process and procedures and
9 compliance expert. What I'm
10 looking at is, what did you guys
11 write down? Did you follow it?
12 Is there a rationale behind the
13 decisions that were made and does
14 that rationale make any kind of
15 sense? But that's what I'm
16 working on.

17 BY MS. WICHT:

18 Q. So I understand that, and
19 you mentioned yesterday that you're
20 focused on process. And I appreciate
21 that.

22 What I'm trying to get at
23 now, Dr. Whitelaw, is the question of
24 whether -- and certainly you found flaws

1 in Cardinal Health's suspicious order
2 monitoring processes, correct?

3 A. Yes, I did.

4 Q. And we're going to -- we're
5 going to get into those. But what I'm
6 trying to get to now is the question of
7 whether you identified whether those, in
8 your opinion, flawed processes, whether
9 you identified specific results that you
10 contend were improper?

11 MR. BOGLE: Object to form.

12 BY MS. WICHT:

13 Q. So my question is, are there
14 any particular orders that were placed
15 with Cardinal Health that you opine were
16 suspicious and were not reported to DEA?

17 MR. BOGLE: Object to form.

18 THE WITNESS: I am going to
19 go back to the four corners.

20 Again I'm not quite sure what
21 you're trying to -- trying to ask
22 me, because it seems to me to be a
23 two part question.

24 I saw orders that Cardinal

1 Health should have investigated
2 further and didn't see any
3 investigation on it.

4 BY MS. WICHT:

5 Q. Can you identify for me any
6 particular order placed by a Cardinal
7 Health customer that Cardinal Health, in
8 your opinion, should have reported to DEA
9 as suspicious and did not?

10 MR. BOGLE: Object to form.
11 Asked and answered.

12 THE WITNESS: Again, as I
13 said, I identified orders that I
14 saw that should have generated
15 additional due diligence. And
16 what I saw was that that due
17 diligence was not there.

18 BY MS. WICHT:

19 Q. If you had identified
20 specific orders, an order placed by X
21 customer on Y date, would those be
22 included in your report?

23 I'm sorry, let me -- let me
24 rephrase that.

1 If you had identified
2 particular -- a particular order that you
3 believed was suspicious and should have
4 been reported to DEA and was not, would
5 that be reflected in your report?

6 A. Again, I am here as a
7 compliance expert, not drawing legal
8 conclusions. So again I'm not sure what
9 you're asking me.

10 Q. Can you identify for me any
11 order placed by any customer to Cardinal
12 Health that you believe was suspicious
13 and was not reported to DEA?

14 MR. BOGLE: If you need to
15 refer to your report, you can.

16 THE WITNESS: Let's go
17 through the report. We can go
18 through the report and look at the
19 examples that are cited in my
20 report. And I'm going to say --
21 and I'm going to offer you the
22 same answer that I gave you
23 before, which is I saw things that
24 should have generated additional

1 inquiry by Cardinal Health. I did
2 not see the additional inquiry
3 being done.

4 BY MS. WICHT:

5 Q. So, respectfully my time
6 this morning is limited. So I'm not
7 going to take time to go through the
8 report with you right now.

9 But my question is, I take
10 it from your answer then, that if you --
11 to the extent you identified any
12 suspicious orders that you contend should
13 have been reported and were not, they
14 will be identified in your report; is
15 that correct?

16 A. As I said yesterday, and I
17 will make it clear again. The approach
18 to the report is very similar to an
19 audit. There are examples in there
20 indicating, showing the pattern of
21 practice with regards to process and
22 failure to follow process. That's what's
23 in my report.

24 Q. And if there are no specific

1 orders by any Cardinal Health customers
2 identified in your report as suspicious,
3 but not reported to DEA, then it's fair
4 to assume that you did not identify any,
5 correct?

6 MR. BOGLE: Object to form.

7 THE WITNESS: Again, let's
8 go through the report and take a
9 look at. I'm still having --
10 struggling with your question.
11 So, I'm sorry.

12 BY MS. WICHT:

13 Q. Are you offering any
14 opinions, Dr. Whitelaw, concerning the
15 specific thresholds that Cardinal Health
16 set for any particular customer?

17 MR. BOGLE: Object to form.

18 THE WITNESS: Am I offering
19 any opinions about the thresholds?

20 BY MS. WICHT:

21 Q. Are you --

22 A. I -- you -- can you be more
23 specific please?

24 Q. Are -- yes. Are you

1 offering any opinions about the
2 thresholds that Cardinal Health set for a
3 specific customer, in other words, are
4 you offering an opinion that the
5 threshold for a particular pharmacy was X
6 and it should have been X minus 100?

7 MR. BOGLE: Object to form.

8 BY MS. WICHT:

9 Q. Are you offering any
10 opinions of that nature with regard to
11 Cardinal Health?

12 MR. BOGLE: Same objection.

13 THE WITNESS: Again, as I've
14 tried to be clear, the opinions
15 I'm offering with regards to,
16 let's just take thresholds, would
17 have been what's the documentation
18 behind it to justify setting a
19 threshold at X.

20 BY MS. WICHT:

21 Q. So I understand, you're --
22 you're -- you've made clear that what
23 you're talking about is process.

24 What I'm trying to get to,

1 sir, is the outcome of that process.

2 I understand you believe
3 Cardinal Health's process for setting and
4 adjusting thresholds had flaws, correct?

5 A. Yes.

6 Q. Have you identified any
7 threshold for any Cardinal Health
8 customer that you believe was
9 inappropriately set --

10 A. Again --

11 MR. BOGLE: Just wait --

12 BY MS. WICHT:

13 Q. -- as a result of the
14 process flaws that you identified?

15 A. Again, outside the setting
16 of the actual number on whether it's
17 right or wrong, is outside of the scope
18 of what I was asked to look at.

19 Q. And you're not offering any
20 opinions as I understand it,
21 Dr. Whitelaw, that any particular
22 shipment of opioids by Cardinal Health
23 was, in fact, diverted, correct?

24 A. Again, my limit, the limits

1 that I was asked to do, was look at
2 process, and whether the process was
3 followed. I am not drawing any legal
4 conclusions. I am simply noting the
5 process flaws and issues with the
6 current -- with the process that I
7 observed.

8 Q. I don't think I'm asking you
9 about any legal conclusions. I'm asking
10 you whether, as a factual matter, there's
11 any shipment of opioids by Cardinal
12 Health that you are opining was, in fact,
13 diverted to illegitimate use.

14 A. Again, you know the scope of
15 the report. It was outside of the scope.
16 I was not looking at that. I was looking
17 at the process and whether the process
18 was being followed.

19 Q. Okay. Now, your report,
20 sir, lays out a variety of ways that you
21 believe Cardinal Health's anti-diversion
22 program was not effective, correct?

23 A. Yes.

24 Q. And I take it from the

1 testimony that you gave yesterday, that
2 you would agree with the premise that
3 there is no one correct way to run an
4 anti-diversion program, correct?

5 MR. BOGLE: Object to form.

6 THE WITNESS: I would agree
7 with the premise that any
8 anti-diversion program needs to be
9 tailored to the individual
10 company, which is consistent with
11 my experience as a compliance
12 expert and certainly fits with the
13 guidance that I have seen from the
14 DEA and others.

15 BY MS. WICHT:

16 Q. So anti-diversion systems or
17 practices, you would expect them to vary
18 from company to company, correct?

19 A. I would expect them to be
20 tailored appropriately to the -- from
21 company to company.

22 Q. And you would expect, even
23 the anti-diversion processes and systems
24 within one company to vary over time,

1 correct?

2 MR. BOGLE: Object to form.

3 THE WITNESS: What do you
4 mean by "vary over time"?

5 BY MS. WICHT:

6 Q. You would expect them to
7 change over time to account for changing
8 circumstances, correct?

9 MR. BOGLE: Object to form.

10 THE WITNESS: Well, to
11 clarify, I would expect to see if
12 they are going to change, that
13 there would be improvement over
14 time.

15 BY MS. WICHT:

16 Q. So there's not, in your
17 opinion, one correct form for an
18 anti-diversion system against which you
19 compared Cardinal Health and found them
20 lacking, correct?

21 MR. BOGLE: Object to form.

22 BY MS. WICHT:

23 Q. That wasn't the nature of
24 the analysis that you did?

1 MR. BOGLE: Object to form.
2 Misstates testimony.

3 THE WITNESS: Could you ask
4 the question again? I lost the
5 train of thought.

6 BY MS. WICHT:

7 Q. Sure. You are not -- the
8 nature of your analysis was not to
9 compare Cardinal Health's anti-diversion
10 processes against one -- against a one
11 correct formula for a program and find
12 them wanting as compared to that one
13 correct formula, correct?

14 MR. BOGLE: Objection.
15 Misstates the testimony.

16 You can answer.

17 THE WITNESS: As I said,
18 there is -- the standard is the
19 same for having -- you have to
20 have an effective anti-diversion
21 program. That is going -- how you
22 implement that will vary from
23 company to company. It must be
24 tailored to the company.

1 BY MS. WICHT:

2 Q. You testified yesterday
3 about companies speaking with the
4 regulators who oversee their activities.
5 Seeking guidance from the regulators who
6 oversee their activities. Do you recall
7 that subject generally from yesterday?

8 A. I do recall that subject
9 generally.

10 Q. Okay. And I believe you
11 testified that you were aware that some
12 of the registrants involved in this case
13 communicated with DEA from time to time
14 to seek input about suspicious order
15 monitoring, correct?

16 A. I'd say that's a fair
17 characterization.

18 Q. And I believe you also
19 testified yesterday that there's
20 nothing -- there's nothing improper about
21 that, correct, about communicating with
22 regulators and seeking guidance from
23 them?

24 A. No. There's nothing

1 improper about doing it. As I said
2 before, good communication is important.

3 Q. Okay. So -- and I
4 understand that we had a discussion
5 yesterday about whether or not regulators
6 should respond to those types of
7 communications. And I'm not going there.
8 I'm leaving that to the side.

9 My question for you, though,
10 is, if the regulator does respond and
11 provides information or guidance back to
12 the registrant, would you agree that the
13 registrant should be able to rely on
14 what's said to them by the regulator?

15 MR. BOGLE: Objection.

16 Vague and overbroad.

17 THE WITNESS: Could you be a
18 bit more precise, please?

19 BY MS. WICHT:

20 Q. Sure. So if, for example, a
21 registrant has a conversation with a
22 regulator about the nature of their
23 suspicious order monitoring systems, and
24 the regulator says, you're doing the

1 right thing, you're headed in the right
2 direction.

3 Do you agree that the
4 company should be able to rely on that
5 statement from the regulator?

6 A. I think you're going to have
7 to give more context to what that
8 communication looks like before I can
9 give you a response.

10 Do you have a specific fact
11 pattern, or is there a document that
12 you'd like me to look at?

13 Q. Well, should the
14 registrant -- when a registrant
15 communicates with DEA, are they entitled
16 to assume that DEA is not lying to them
17 in response?

18 MR. BOGLE: Object to form.

19 THE WITNESS: Again, can
20 we -- you're talking about all
21 communications, any kind of
22 contact. I think we need to
23 narrow that field, and what in
24 particular are you looking at? Do

1 you have a particular fact pattern
2 that you'd like me to talk about?
3 Or is there a particular document
4 that you'd like me to work with?

5 BY MS. WICHT:

6 Q. I'm talking about
7 communications with DEA concerning
8 suspicious order monitoring practices.

9 If a registrant has a
10 communication with DEA about their
11 suspicious order monitoring practices, is
12 the registrant entitled to rely on
13 whatever information or input DEA
14 provides back to them?

15 MR. BOGLE: Object to form.
16 Vague and overbroad.

17 THE WITNESS: All right.
18 Let me try to ask some questions
19 that might help me answer your
20 question.

21 Is there a particular person
22 or position that we are talking
23 about that communication
24 occurring? Are we talking at the

1 investigator level? The district
2 office level? Headquarters level?
3 When you say DEA, they employ a
4 large number of employees. So I'm
5 having trouble figuring out what
6 you're really seeking information
7 on.

8 BY MS. WICHT:

9 Q. Does it matter? Are
10 registrants entitled to rely on
11 headquarters but not entitled to rely on
12 field agents or vice versa?

13 A. I think as I tried to make
14 clear yesterday, policy -- when you're
15 looking for policy pronouncements, those
16 need to come from headquarters. And
17 those usually do come from headquarters.

18 Again, it does happen.
19 People are people. If you get something
20 that didn't make sense or the answer that
21 you get doesn't make sense compared to
22 what you know the policy is, then you
23 need to seek clarification up the chain
24 of command until you get a policy

1 response.

2 Q. I want to talk about your
3 report for -- turn to your report,
4 Dr. Whitelaw, which is marked as
5 Exhibit 2.

6 A. Is there a specific page?

7 Q. On Page 45.

8 A. I'm there.

9 Q. In the last paragraph before
10 Section 8.2, you offered the opinion that
11 Cardinal Health, among other customers,
12 scored no higher than the midpoint of the
13 foundational level on your compliance
14 maturity and program effectiveness model,
15 correct?

16 A. That's what I opined, yes.

17 Q. When you offered that
18 opinion, are you -- does your opinion
19 relate to the suspicious order monitoring
20 program, the controlled substances
21 compliance program, or the corporate
22 compliance program as a whole? And I'm
23 referring to the three components of your
24 Russian nesting dolls.

1 A. And I would say it relates
2 to all three components because they're
3 all interrelated and all interconnected.

4 Q. Okay. So you're offering an
5 opinion about Cardinal Health's -- not
6 just Cardinal Health suspicious order
7 monitoring program, but also its
8 controlled substances compliance program
9 and its corporate compliance program,
10 correct?

11 A. Again, as we've talked about
12 under the Russian nesting dolls, if
13 one -- you can't claim you have an
14 effective -- we'll start at the top of
15 the house. You can't claim that you have
16 an effective corporate compliance program
17 if you do not have an effective
18 anti-diversion program, and if you do not
19 have an effective suspicious order
20 monitoring program. They all nest
21 together. They're all interrelated.
22 They're all interconnected.

23 Q. So as part of your
24 evaluation of Cardinal Health's overall

1 controlled substances compliance program,
2 did you make any evaluation of the
3 company's practices with respect to
4 physical security for opioids?

5 A. Again, I was looking
6 primarily -- the focus was suspicious
7 order monitoring and moving from there.
8 So again, if the suspicious order
9 monitoring program is a problem, the
10 anti-diversion program is not a -- can't
11 be deemed to be effective, neither can
12 the corporate compliance program be
13 deemed effective. That is the opinion
14 that I am offering.

15 Q. Okay. So then, I take it
16 from your answer then, that things
17 outside of the suspicious order
18 monitoring component of the controlled
19 substances compliance program, you did
20 not look at, correct?

21 MR. BOGLE: Object to form.

22 THE WITNESS: To your
23 specific question about whether I
24 looked at physical and vault

1 security, I did not.

2 BY MS. WICHT:

3 Q. Did you look at Cardinal
4 Health's compliance with regulations
5 related to security and transport of
6 opioids?

7 A. I did not. It was outside
8 of the scope of what I was asked to look
9 at.

10 Q. Did you look at Cardinal
11 Health's practices with respect to theft
12 and loss of controlled substances?

13 A. Again, it was not in the
14 scope of what I was asked to look at.

15 Q. So what I'm trying to
16 understand versus going through all of
17 these individually, is that you did not
18 look at compliance practices and
19 processes outside of the suspicious order
20 monitoring function; is that correct?

21 MR. BOGLE: Object to form.
22 Misstates the report.

23 THE WITNESS: I think the
24 better way to characterize it, to

1 try to be helpful to you, is the
2 focus was on suspicious order
3 monitoring, as well as those
4 things in the anti-diversion
5 program and those in the corporate
6 compliance program that would bear
7 on it.

8 Again, as I've said before,
9 this is an integrated system. And
10 so trying to tease out one bucket
11 versus another bucket versus
12 another bucket, which is why the
13 diagram is drawn the way it is,
14 you cannot separate them from each
15 other. They are an integrated
16 whole.

17 BY MS. WICHT:

18 Q. So fair to say that you did
19 not evaluate practices or processes in
20 Cardinal Health's compliance program
21 except to the extent that they related to
22 suspicious order monitoring, correct?

23 MR. BOGLE: Object to form.

24 THE WITNESS: I think that

1 misstated what I said to the
2 extent that it related to or
3 impacted on suspicious order
4 monitoring, I did evaluate those.

5 BY MS. WICHT:

6 Q. Well, that's what I said.
7 To the extent that they related to
8 suspicious order monitoring.

9 A. And I'm adding the term "or
10 impacted" to be precise with you.

11 Q. Okay. If you would turn to
12 Page 100 of your report, please.

13 This is your section that's
14 specific to Cardinal Health, correct?

15 A. Yes.

16 Q. And on Page 100 and 101 you
17 refer to a couple of enforcement actions
18 against Cardinal Health. Do you recall
19 that?

20 A. Yes, ma'am, I do recall
21 referring to those enforcement actions.

22 Q. Now, none of the enforcement
23 actions against Cardinal Health that you
24 discuss occurred in Cuyahoga County or

1 Summit County, Ohio, correct?

2 A. That is correct.

3 Q. And none of the -- well, do
4 you know what -- which Cardinal Health
5 distribution center primarily served
6 Cuyahoga County and Summit County?

7 A. I'd have to go back and look
8 at my report, but not off the top of my
9 head, I do not.

10 Q. Okay. If I tell you it was
11 Wheeling, West Virginia, does that sound
12 familiar to you or do you think that's
13 something that you were aware of?

14 A. If you tell me Wheeling --
15 Wheeling, West Virginia, the name sounds
16 familiar, but again I cannot, without
17 doing more digging definitively answer
18 your question for you.

19 Q. And are you aware that none
20 of the enforcement actions against
21 Cardinal Health that you refer to in your
22 report concern the Wheeling, West
23 Virginia, distribution center?

24 MR. BOGLE: Object to form.

1 THE WITNESS: Yes, I'm aware
2 of that.

3 BY MS. WICHT:

4 Q. Now, you testified about
5 Section 10.2 of your report is the
6 executive summary as to Cardinal Health,
7 correct?

8 A. Yes, that's what it states.

9 Q. And if I understood your
10 testimony yesterday, this section is
11 basically an attempt to summarize,
12 provide an executive summary of the
13 detail regarding Cardinal Health that
14 follows in the rest of the section; is
15 that correct?

16 A. I would say that is correct.

17 Q. Okay. And you -- so some of
18 your opinions that you summarize in the
19 executive summary about Cardinal Health,
20 one of your opinions is that Cardinal
21 Health was over reliant on technology in
22 controlled substances compliance efforts?

23 A. May I ask -- may I ask where
24 you're reading from?

1 Q. Yes, sir. Page 101. The
2 first full paragraph on the page.

3 A. I see the paragraph. I'm
4 there.

5 Q. And -- and one of your
6 opinions is that Cardinal Health's over
7 reliance on technology played a prominent
8 role in what you believe to be the
9 failure of its controlled substance
10 compliance program, correct?

11 A. I believe it played a role,
12 yes.

13 Q. And then if we go down to
14 the next paragraph below that, which is
15 just a one-sentence paragraph, you say,
16 "In the case of technology, Cardinal
17 placed a premium on its analytical
18 systems to detect suspicious orders and
19 potential diversion while neglecting the
20 importance of the human element and
21 making sense from the data outputs."

22 Do you see that?

23 A. Yes, I do.

24 Q. And that's your opinion?

1 A. That is my opinion.

2 Q. So I want to turn, sir, to
3 some of the detail about Cardinal Health
4 provided in your report. And if you
5 would turn to Page 117, please.

6 A. I'm there.

7 Q. If you look at the second
8 paragraph on that page, you may recall we
9 talked about this a bit yesterday where
10 you identify the fact that Cardinal's
11 process doesn't define significantly
12 larger, significantly more frequent, and
13 significant deviation. Are you with me?

14 A. I'm there.

15 Q. Okay. And then you say, "In
16 all" -- at the end of that paragraph:
17 "In all three cases, the standard
18 operating procedure just required QRA
19 personnel to use available information
20 and experience to make reportability
21 determinations."

22 Do you see that?

23 A. I do.

24 Q. And if you look at the

1 beginning of that section on the report,
2 it appears to me that the time frame that
3 your criticism is directed at is from
4 2008 through 2016. Would you agree with
5 that?

6 A. Where are you looking
7 please?

8 Q. I'm looking at the beginning
9 of that Section B, "Threshold Events."
10 You say, "During this period Cardinal
11 Health implemented certain SOPs and they
12 ultimately retired them in 2016"?

13 A. Could you restate -- could
14 you repeat -- repeat the question for me
15 please?

16 Q. Sure. So your criticism,
17 one of your criticisms on Page 117 is
18 that the SOP in your view was faulty in
19 that it required Cardinal Health's QRA
20 personnel to use available information
21 and experience to make decisions,
22 correct?

23 MR. BOGLE: Object to form,
24 misstates the document.

1 THE WITNESS: No, that's not
2 correct.

3 The issue wasn't the fact
4 that it asked the QA -- RA
5 personnel to use available
6 information and experience. The
7 problem with the SOP is it doesn't
8 provide any kind of boundaries or
9 guidelines on what available
10 information to look -- look at and
11 how to make those decisions. So
12 there's no decisionmaking
13 criteria. There's no set of
14 documents to evaluate. There's no
15 consistent process to be applied
16 which leads to inconsistency in
17 decisions between one person and
18 another person, if you don't
19 provide any sort of boundary lines
20 or goalposts. That's -- that's
21 basic compliance work, is to try
22 to create consistency in the
23 systems. You do that by putting
24 out criteria for people to follow,

1 so that Person A and Person B
2 achieve the same outcome on the
3 same set of facts.

4 BY MS. WICHT:

5 Q. Okay. Well, so let's talk
6 about that, sir. On Page 124 of your
7 report. At the very top of the page, you
8 talk about some work instructions for
9 Cardinal Health anti-diversion personnel.

10 Do you see that, sir?

11 A. I do.

12 Q. And you fault the work
13 instructions, you find fault with the
14 work instructions for providing what you
15 call a loophole where [REDACTED]

16 [REDACTED],
17 correct?

18 A. I'd say that's a fair
19 characterization.

20 Q. And do you recall that those
21 work instructions provide significant --
22 well, let me strike that.

23 Do you recall the guidance
24 that is provided in the work instructions

1 for when [REDACTED]
[REDACTED]

3 A. I'd have to look at the
4 document. Do you have a document for me
5 to look at?

6 Q. Sure. You actually attached
7 it to your report, sir. It's in the
8 back. At Appendix D on Page 249. Or at
9 least you attached a snippet of it.

10 Are you there?

11 A. I'm getting there. Yeah,
12 I'm there. Thank you.

13 Q. Okay. Sure. So this isn't
14 the whole document, but I guess it's a
15 clip of it that you -- you felt
16 appropriate to attach to your report.

17 But these are the -- do you
18 recognize these to be the work
19 instructions that provide [REDACTED]
[REDACTED]

21 A. I recognize it to be a table
22 that is taken out of a multi-page
23 document called "The Work Instructions,"
24 yes.

1 Q. Do you recognize it to be
2 the portion of the work instructions
3 that, in fact, [REDACTED]

■ [REDACTED]
■ [REDACTED]

6 A. Again, it's a snippet from a
7 multi-page document. It's a [REDACTED]

■ [REDACTED]

■ [REDACTED] Yes, I do recognize that.
10 It's not the entire document.

11 Q. Agreed. It's -- it's what
12 you saw fit to include in the report.

13 And you agree that that

14 [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED] correct?

18 A. Can you say the question
19 again for me? You lost me somewhere
20 there.

21 Q. Sure. The -- the [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

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[REDACTED]

[REDACTED]

A. It provides some guidance. It's not the complete guidance. As we've discussed, it's a [REDACTED] taken from a multi-page work instruction document.

Q. Is it your opinion that the guidance provided to employees on when

[REDACTED]

[REDACTED]

A. Again, I would have to review the entire work instruction documents. So if you have a copy of that I'll be happy to look through it again.

Q. So the snippet of a document that you chose to include in your report is not sufficient for you to make that determination; is that correct?

MR. BOGLE: Object to form.

THE WITNESS: The snippet of the document that I included was to show [REDACTED] It wasn't necessarily to describe all

1 the guidance provided in the work
2 instruction.

3 BY MS. WICHT:

4 Q. I'm not asking you about all
5 the guidance provided in the work
6 instructions, sir. I'm asking you about
7 the guidance provided about when

8 [REDACTED]

9 [REDACTED]

10 As I understand your
11 testimony, you're telling me that the
12 portion of the information that you
13 included in your report is not sufficient
14 to allow you to form an opinion about
15 whether that guidance was adequate,
16 correct?

17 MR. BOGLE: Object to form.

18 THE WITNESS: I think as I
19 keep trying to convey to you you
20 need to look at the entire work
21 instruction.

22 BY MS. WICHT:

23 Q. But you didn't put the
24 entire work instruction in the table of

1 your report, correct?

2 A. I didn't put the entire
3 document of all the documents in my
4 report, so I'm not exactly sure what your
5 point is, Counselor.

6 Q. You quote -- back on Page
7 101 in the executive summary of your
8 report. You quote some testimony by
9 Mr. George Barrett, the former CEO of
10 Cardinal Health on Page 101.

11 Do you see that?

12 A. Where are you looking in
13 particular?

14 Q. I'm looking at the indented
15 block quotes on Page 101.

16 A. I see them.

17 Q. Did you review
18 Mr. Barrett's -- the entirety of
19 Mr. Barrett's testimony to Congress?

20 A. Yes, as a matter of fact, I
21 did read the entire document.

22 Q. Okay. Do you recall
23 Mr. Barrett testifying that Cardinal
24 Health has terminated or refused to

1 distribute controlled substances to over
2 a thousand pharmacies? Did you see that
3 testimony?

4 A. I'm sure I did see it. I
5 read the whole document. But I would
6 have to see it again to refresh my
7 recollection.

8 (Document marked for
9 identification as Exhibit
10 Whitelaw-14.)

11 MR. BOGLE: What's the
12 exhibit number?

13 MS. WICHT: 14.

14 BY MS. WICHT:

15 Q. And I'll ask you to turn,
16 sir, to Page 5 --

17 A. May I have --

18 Q. -- of that testimony.

19 A. May I have a minute to
20 review the whole document?

21 Q. No. If you're going to read
22 the whole document, I'm not going to ask
23 the question. Because I don't have time.

24 MR. BOGLE: You're entitled

1 to read the document.

2 THE WITNESS: I'm going to
3 read the whole document, so --

4 BY MS. WICHT:

5 Q. Okay. Then let's move on.
6 Do you recall, without reading the entire
7 document, Mr. Barrett testifying that
8 Cardinal Health had terminated or refused
9 to distribute controlled substances to
10 over a thousand pharmacies?

11 A. As I said before, I would
12 need the whole document to refresh my
13 recollection. But we apparently don't
14 have time.

15 Q. Okay. So you don't --
16 sitting here right now, you don't recall
17 that testimony?

18 A. I can't recall it off the
19 top of my head.

20 Q. Sitting here today, do you
21 recall Mr. Barrett's testimony on Page 5
22 of his written testimony that from 2008
23 to the present, Cardinal Health had
24 stopped suspicious orders for the

1 shipment of hundreds of millions of
2 dosage units of controlled substances?

3 Do you recall that?

4 A. Again, without looking at
5 the document, I -- I've read a lot of
6 documents. I can't precisely recall what
7 he said, all of the statements in that
8 testimony.

9 Q. You're welcome to look at
10 Page 5 of the written testimony, which is
11 where those appear, sir, but I'm not
12 going to ask you about anything else in
13 the document, so I'm not going to have
14 you take the time to read through the
15 whole thing.

16 But you opined in your
17 report that -- well, let me -- let me
18 strike that.

19 Did you consider those
20 facts, those two facts offered by
21 Mr. Barrett in forming your conclusions
22 Cardinal Health's suspicious order
23 monitoring program?

24 A. I'm sure I considered those

1 facts in looking again at Mr. Barrett's
2 testimony. I read his testimony from
3 beginning to end. So at some point it
4 had to have factored in.

5 Q. So would you agree that
6 those facts are relevant to your analysis
7 of whether Cardinal Health -- and I'm
8 quoting from Page 101 of your report --
9 that Cardinal Health developed a program
10 that was -- allowed Cardinal to "avoid
11 identifying orders as suspicious and
12 continue supplying customers that it knew
13 or should have known were engaging in
14 diversion-related behavior"?

15 A. Can you be more specific?
16 What are you looking for, Counsel?

17 Q. My question is, whether
18 those facts as testified to by
19 Mr. Barrett in Congress, do you agree
20 that those facts are relevant to your
21 conclusion that Cardinal Health was
22 attempting to avoid identifying orders as
23 suspicious and continue supplying
24 customers it knew or should have known

1 were engaged in diversion?

2 A. Well, again, you're --
3 information is always relevant and needs
4 to be considered. In this particular
5 case, I have no way of verifying
6 Mr. Barrett's statements one way or the
7 other.

8 I looked at the record of
9 the other -- the totality of the record,
10 including Mr. Barrett's statements in
11 coming -- in forming my opinions. I
12 didn't just form it off of a single piece
13 of paper.

14 Q. So when you opined that
15 Cardinal Health was attempting to avoid
16 identifying orders as suspicious and
17 continue supplying customers it knew were
18 diverting, did you consider the number of
19 customers that Cardinal Health has cut
20 off from supplying controlled substances?

21 MR. BOGLE: Objection.

22 Asked and answered. You can
23 answer again.

24 THE WITNESS: Again, I

1 looked at the totality of the
2 record. And as I said to you, I
3 did read Mr. Barrett's testimony
4 as part of the record I looked at
5 in forming my opinions.

6 BY MS. WICHT:

7 Q. How many customers do you
8 think Cardinal Health should have cut
9 off, if it had an effective -- in your
10 view, effective suspicious order
11 monitoring system?

12 A. I'm not here to opine on a
13 specific number. As I said I was looking
14 at process and failure to follow process,
15 and whether the process was robust or
16 not. I have no way of knowing what the
17 right number of customers to be
18 terminated would have been.

19 Q. And I take it your answer
20 would be the same if I asked the question
21 about suspicious order reporting as
22 opposed to termination of customers,
23 correct?

24 MR. BOGLE: Object to form.

1 THE WITNESS: Again, I
2 looked at process, whether you
3 followed the process, whether
4 there's enough to understand how
5 the process worked.

6 So my answer would be
7 exactly the same. I'm not here to
8 tell you what is the right number
9 of suspicious orders.

10 BY MS. WICHT:

11 Q. If you would turn, sir, to
12 Page 104 of your report. This is the
13 section of your report that's about your
14 opinions about Cardinal Health's culture?

15 A. Yes.

16 Q. Are you there?

17 A. I'm there.

18 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
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[REDACTED]

[REDACTED]

Q. Did you review any testimony about that e-mail that you can recall?

A. Again, I've reviewed a lot of testimony, so I can't say if I've reviewed a specific piece of testimony or not.

Q. Fair enough. And you cited that particular e-mail as an example in your report of one of the flaws -- or of Cardinal Health's flawed corporate culture, correct?

A. I cited it as an example, yes.

Q. Did you -- well, are you -- you're familiar with a Cardinal Health employee named Gilberto Quintero?

A. Yes, I am familiar with him.

Q. And -- and that -- looking at your reliance list, I don't believe you reviewed Mr. Quintero's testimony in

1 this case at all; is that correct?

2 A. Again, I would have to go
3 back to the reliance list.

4 Q. Feel free to do that, sir.
5 The list of depositions is on Page 276
6 and 277.

7 A. I don't see it on my list.

8 Q. Okay. So you didn't review
9 the testimony given by Mr. Quintero in
10 this matter then, correct?

11 A. To the best of my knowledge,
12 relying on my reliance list, no.

13 Q. Okay. So then, you're not
14 aware, I assume, since you didn't review
15 the testimony, that Mr. Quintero
16 testified that that statement by
17 Mr. Mahoney was not true, correct?

18 A. I am not aware of that
19 statement.

20 Q. Did you review any testimony
21 by Mr. Reardon regarding this e-mail?

22 A. Again, I'd have to go back
23 to the reliance list.

24 Q. And Mr. Reardon is on your

1 list, so I'll represent to you that it
2 appears to me that -- well, all I can say
3 is he's on your list. That should mean
4 that you reviewed his testimony, correct?

5 A. I reviewed his testimony.

6 Q. Okay. Do you recall
7 Mr. Reardon testifying that he never said
8 to Mr. Mahoney that Cardinal Health does
9 not report suspicious orders?

10 A. I do not recall it. But
11 again I've reviewed a lot of depositions
12 and testimony. So I can't say I recall
13 it off the top of my head.

14 Q. I'm happy to show it to you
15 if you'd like to see it.

16 A. Sure.

17 Q. Okay.

18 (Document marked for
19 identification as Exhibit
20 Whitelaw-15.)

21 MS. WICHT: Sorry, I'm not
22 trying to throw it at you.

23 BY MS. WICHT:

24 Q. This is Exhibit Number 15,

1 which is an excerpt from the testimony of
2 Steve Reardon, a former employee of
3 Cardinal Health.

4 Do you see that?

5 A. I do see that that's what it
6 represents and purports to be, yes.

7 Q. Okay. And on Page 38, which
8 we've provided for you, sir, you can feel
9 free to take a look at the -- the few
10 questions that come before that. You'll
11 see that Mr. Reardon is being questioned
12 about this document.

13 And do you see Mr. Reardon
14 answering questions saying that he did
15 not make the comment that's recited in
16 this e-mail?

17 A. If I can have a second,
18 Counselor, I'm...

19 Q. Sure.

20 A. Yes, I see that he said
21 that.

22 Q. And did you review any
23 testimony by Mr. Mahoney on this e-mail?
24 And I'll represent to you again that

1 Mr. Mahoney does appear in your list of
2 reliance materials.

3 A. I -- I know I reviewed
4 his -- some -- I reviewed his testimony.
5 I can't again recall a specific section
6 out of multiple pages.

7 Q. Are you -- do you recall
8 that Mr. Mahoney testified about this
9 e-mail, "I believe that in my writing
10 this, I misspoke and I was referring to
11 when they shut customers down because
12 they were suspicious customers."

13 Do you recall seeing that in
14 Mr. Mahoney's deposition testimony?

15 A. Again, I don't recall it.

16 (Document marked for
17 identification as Exhibit
18 Whitelaw-16.)

19 BY MS. WICHT:

20 Q. I'll mark it as Exhibit 16,
21 just so that you have it in front of you,
22 sir. Sorry.

23 So this is an excerpt from
24 the testimony of Mr. Mahoney.

1 Do you see that?

2 A. Yes, I see that.

3 Q. And the discussion of the
4 document begins on Page 424, which we've
5 excerpted for you. And do you see, the
6 testimony that I quoted for you is on
7 Page 425?

8 A. I'm getting there. I see
9 it.

10 Q. My question for you, sir, is
11 if all of the participants in this
12 supposed discussion that's recounted on
13 Page 105 of your report deny the accuracy
14 of that e-mail, does that affect your
15 opinion that the e-mail supports the
16 conclusions in your report?

17 A. No, Counselor, it doesn't
18 change my opinion.

19 Q. So the fact that all three
20 individuals who were involved in that
21 conversation deny that it occurred as
22 reported here on Page 105 of your report
23 has no impact on your conclusions about
24 the e-mail?

1 A. Does not change --

2 MR. BOGLE: Let her finish.

3 THE WITNESS: That is
4 correct, it does not change my
5 opinion. Again, we are talking
6 about opinions that are offered
7 after the fact when they are
8 confronted with something that is
9 unpleasant. And there was no
10 attempt made for example, when the
11 original e-mail was written to
12 correct the misstatements that are
13 in the original e-mail.

14 BY MS. WICHT:

15 Q. Well, how do you know that?

16 A. I didn't see anything.

17 Q. Do you know that it doesn't
18 exist?

19 A. No, but I don't know that it
20 didn't -- that it exists or doesn't
21 exist. But I didn't see anything that
22 says there was any contemporaneous
23 attempt to correct the record. And if
24 this was a -- again, standard practice is

1 if you misstate or you make a mistake of
2 this kind of magnitude in an e-mail, you
3 correct it with a follow-up, that is
4 standard practice. That's what I would
5 have expected to see. I did not see it
6 here.

7 Q. So are you then offering an
8 opinion that Mr. Mahoney, Mr. Reardon,
9 and Mr. Quintero all lied under oath?

10 A. No, ma'am.

11 Q. Is that what you're
12 testifying to here today?

13 A. No, ma'am, I'm not. We know
14 the e-mail exists. We know the statement
15 exists.

16 Q. Okay. You in your report,
17 you reach several conclusions about
18 Cardinal Health's standard operating
19 procedures, correct? And I'm referring
20 to -- I'll direct you to Section 10.5.1
21 of your report, which begins on Page 108.

22 A. Okay.

23 Q. And you say in the third
24 paragraph on that page, you describe

1 Cardinal Health's anti-diversion program
2 from 2007 to 2012 as convoluted and you
3 state that it was difficult to determine
4 across the five key SOPs that comprised
5 the program where one ends and the other
6 begins.

7 Do you see that opinion?

8 A. Yes, I do.

9 Q. And that's your opinion,
10 correct?

11 A. That is my opinion.

12 Q. Okay. Are you familiar with
13 Mr. Michael Moné, a Cardinal Health
14 employee?

15 A. Yes.

16 Q. And you are aware that
17 Mr. Moné had, as I think you described it
18 on Page 107, Mr. Moné had operational
19 responsibility for the controlled
20 substances program during this period of
21 time, correct?

22 A. I recall that, yes.

23 Q. Okay. And Mr. Moné was --
24 do you recall that Mr. Moné was listed as

1 an approver on most of the standard
2 operating procedures that you reviewed
3 from this period of time?

4 A. I would have to go back and
5 look at the actual documents to confirm
6 that, Counselor. So no, I don't recall
7 it off the top of my head.

8 Q. Now, you didn't review any
9 testimony by Mr. Moné in connection with
10 your work in this case, correct?

11 A. Again, let's go back to the
12 reliance list.

13 Q. Well, I can represent to you
14 that he's not on the reliance list,
15 because -- are you aware that plaintiffs
16 chose not to take Mr. Moné's deposition
17 in this case?

18 A. No, Counselor, I was not
19 aware of that.

20 Q. Okay. So obviously if his
21 deposition wasn't taken, then you didn't
22 review it, correct?

23 A. Obviously.

24 Q. So you don't know whether

1 Mr. Moné views the standard operating
2 procedures as convoluted, correct?

3 A. No, Counselor, I do not.
4 But the relevant statement -- what
5 you're -- the relevance here, from a
6 compliance perspective, is I, as an
7 outsider, or a new employee, put myself
8 in a new employee's shoes, should be able
9 to read the documents on their face and
10 understand them, and I'm afraid, as I
11 read them and I've read lots of SOPs in
12 my career, written lots of SOPs in my
13 career, I had trouble understanding it.

14 So if I'm having trouble
15 understanding it, I don't know how you
16 explain it to a more junior -- you know,
17 to the basic members of staff.

18 MS. WICHT: Move to strike
19 everything after, "No, Counselor,
20 I do not."

21 BY MS. WICHT:

22 Q. So SOPs are not directed at
23 the outside world, are they,
24 Dr. Whitelaw?

1 MR. BOGLE: Object to form.

2 THE WITNESS: SOPs are
3 directed both internally and
4 externally. You write them for
5 two audiences normally. You write
6 them to instruct staff on what
7 they're doing. But you're also
8 writing them because you're going
9 to be evaluated on them by
10 regulators and others to show you
11 have a system, an adequate and
12 effective system and process in
13 place and that you're following
14 that process.

15 BY MS. WICHT:

16 Q. Now, you -- although you
17 didn't review any testimony by Mr. Moné,
18 obviously. You did review the testimony
19 of various individuals who reported to
20 Mr. Moné, correct?

21 A. I did.

22 Q. Including Mr. Morse,
23 Mr. Forst, a variety -- Mr. Rausch.

24 Do those -- are those names

1 familiar to you as people who reported to
2 Mr. Moné?

3 A. Yes, those names are
4 familiar to me.

5 Q. You reviewed their
6 testimony, correct?

7 A. Yes.

8 Q. Okay. Do you recall seeing
9 any testimony by any of those individuals
10 that they didn't understand Cardinal
11 Health's SOPs?

12 A. Without reviewing each of
13 their individual testimonies again, off
14 the top of my head, I do not recall.

15 Q. If you would turn to your
16 reliance list and to the deposition
17 transcripts that you reviewed again, sir,
18 on Page 276 and 277.

19 A. 276, yes.

20 Q. Okay. Are you familiar with
21 an individual named Kimberly
22 Anna-Soisson, a director of regulatory
23 management at Cardinal Health?

24 A. I am -- that name does ring

1 a bell.

2 Q. But her deposition is not
3 one of the ones that you reviewed,
4 correct?

5 A. It's not on my list that I
6 can see.

7 Q. Are you familiar with a
8 former Cardinal Health employee named
9 Doug Emma, a manager -- excuse me -- a
10 manager within the regulatory department?

11 A. Again, without going through
12 the section and looking at all the names,
13 I don't remember the name off the top of
14 my head.

15 Q. Okay. And you didn't review
16 any deposition testimony by Mr. Emma,
17 correct?

18 A. I don't see it on my
19 reliance list.

20 Q. How about Shirleen Justice,
21 a new account specialist in quality and
22 regulatory affairs, did you review any
23 testimony -- are you familiar with
24 Ms. Justice, first of all?

1 A. The name doesn't ring a bell
2 Counselor. We can go down my reliance
3 list.

4 Q. Did you review her
5 deposition testimony?

6 A. If it's not on my reliance
7 list, then I did not review her
8 testimony.

9 Q. Okay. I'll represent that
10 it's not on the list.

11 And we already established
12 that you didn't review any testimony by
13 Mr. Quintero, the senior vice president
14 of QRA at Cardinal Health, correct?

15 A. Yes.

16 Q. And are you familiar with a
17 gentleman named Rich Ryu, spelled R-Y-U,
18 a director of advanced analytics in
19 Cardinal Health's quality and regulatory
20 affairs department?

21 A. Again, the name -- I've
22 reviewed so many documents from so many
23 people. I don't recall the name rightly.

24 Q. But you didn't review

1 Mr. Ryu's deposition transcript, correct?

2 A. Let me look at my reliance
3 list again.

4 Q. Sure.

5 A. No, Jennifer, I did not
6 review the testimony according to my
7 reliance list.

8 Q. Okay. How about Mr. Craig
9 Baranski, the director of operations for
10 the Wheeling, West Virginia, distribution
11 center at Cardinal Health? You didn't
12 review his testimony either, did you?

13 A. Again, I'm going to go back
14 through the list. Again, I don't see his
15 name on my list.

16 Q. Just two more. It's getting
17 a little tedious here. How about Ray
18 Carney, the director of independent
19 retail sales for the Wheeling, West
20 Virginia, distribution center at Cardinal
21 Health? Did you review his deposition
22 testimony?

23 A. Again, I don't see it on my
24 list.

1 Q. And how about Thomas
2 Convery, who was a pharmacy business
3 consultant that was in the sales
4 organization? Did you review his
5 testimony?

6 A. I don't see him on my list.

7 Q. Okay. So we've gone through
8 now a list of nine individuals from
9 Cardinal Health. Now, were you aware of
10 whether or not those individuals provided
11 testimony in this case?

12 A. Counselor, I don't rightly
13 recall the list of everybody who produced
14 testimony or not in this case. So like I
15 said, I've looked at so many depositions.
16 I can't tell you off the top of my head.

17 Q. So four of those individuals
18 worked directly in Cardinal Health's
19 anti-diversion program. And then there
20 was Mr. Moné, who was obviously the --
21 had operational responsibility for the
22 program.

23 Do you think it would have
24 been helpful to review testimony from

1 those individuals before you reached
2 conclusions about Cardinal Health's
3 anti-diversion program?

4 MR. BOGLE: Object to form.

5 THE WITNESS: I --

6 Counselor, without knowing what's
7 in the depositions, I can't make a
8 statement one way or the other on
9 that.

10 BY MS. WICHT:

11 Q. Okay. Fair to say, if
12 you -- it's possible that if you reviewed
13 deposition testimony from those six
14 individuals or maybe even all nine of the
15 individuals who I listed about Cardinal
16 Health's anti-diversion program, do you
17 think it's possible that your opinions
18 would be different?

19 MR. BOGLE: Object to form.

20 THE WITNESS: Anything is
21 possible. But I don't see
22 anything that would have changed
23 my overall conclusion that the
24 SOPs, for example, were difficult

1 and convoluted to read. That
2 would not have changed, depending
3 on what they had to say about it.

4 MS. WICHT: Move to strike
5 after -- everything after,
6 "Anything is possible."

7 BY MS. WICHT:

8 Q. So I want to go back to a
9 subject that you touched on previously a
10 moment ago. You testified yesterday, I
11 believe -- please correct me if I'm
12 wrong -- that DEA did not provide precise
13 definitions of unusual size, unusual
14 frequency, or substantial deviation from
15 a normal pattern. Do you recall that
16 testimony from yesterday?

17 A. I do.

18 Q. Generally?

19 A. Generally.

20 Q. Okay. And I think you
21 said -- again, please correct me if I'm
22 wrong -- that it would be impossible for
23 DEA to give a blanket definition of those
24 words, because it's too fact dependent;

1 is that correct?

2 A. That's not exactly -- that
3 is not what I said. What I said is DEA
4 does not give that, because they're
5 writing a regulation. My understanding,
6 they're writing a regulation for multiple
7 different companies and multiple
8 different business models. And so the
9 regulation is written in more general
10 terms.

11 Q. And then you were asked
12 about the fact that Cardinal Health's
13 SOPs used the words "significantly
14 larger." That's on Page 117 of your
15 report.

16 A. I see it.

17 Q. And I believe your testimony
18 yesterday was that you believed that,
19 unlike DEA, who is writing for the entire
20 registrant community, you believed that
21 Cardinal Health should be able to provide
22 additional granularity in its SOPs since
23 they only relate to Cardinal Health's
24 customers; is that correct?

1 A. I believe Cardinal Health
2 should know Cardinal Health's customers
3 and be able to provide some criteria of
4 what those generic terms mean, yes.

5 Q. Now, as you recited in your
6 report, Cardinal Health has -- serves
7 more than 26,000 pharmacies, correct?

8 A. What page are we on?

9 Q. 100.

10 A. I see it.

11 Q. And again, as you describe
12 it in your report in the paragraph above
13 that, those customers might include
14 hospitals, correct?

15 A. They might.

16 Q. And pharmacies, correct?

17 A. They might.

18 Q. Both retail, independents,
19 and chains?

20 A. That's certainly plausible.

21 Q. And healthcare systems,
22 correct?

23 A. Yes.

24 Q. Ambulatory surgery centers,

1 correct?

2 A. Correct.

3 Q. Clinical laboratories,
4 correct?

5 A. Correct.

6 Q. And physician offices,
7 correct?

8 A. Potentially.

9 Q. And do you believe, of the
10 26,000 pharmacy customers that you cite
11 in your report, are all those customers
12 all approximately the same size, do you
13 believe?

14 MR. BOGLE: Object to form.

15 THE WITNESS: I think you
16 are missing the point.

17 The point was --

18 BY MS. WICHT:

19 Q. I -- I -- respectfully,
20 sir --

21 MR. BOGLE: You can answer
22 the question.

23 BY MS. WICHT:

24 Q. -- I have very limited

1 time --

2 MR. BOGLE: If you want
3 to -- you want to withdraw the
4 question, that's fine. He's going
5 to answer it, otherwise. Your
6 call.

7 MS. WICHT: I withdraw the
8 question.

9 BY MS. WICHT:

10 Q. Is it your opinion that the
11 26,000 pharmacy customers that Cardinal
12 Health serves are all approximately the
13 same size?

14 MR. BOGLE: Object to form.

15 THE WITNESS: Again, as I
16 was saying, you are missing the
17 point.

18 The point here is there
19 needs to be more granularity to
20 very imprecise terms to provide
21 appropriate guidance to the staff
22 responsible for suspicious order
23 monitoring.

24 BY MS. WICHT:

1 Q. Sir --

2 A. That's my point.

3 Q. Sir, I appreciate that you
4 want to jump to the end and give the
5 speech that you want to give. But the
6 way that this works is that I ask
7 questions and you answer the questions
8 that are asked. You don't get to just
9 jump ahead to the end. So let me ask my
10 question one more time.

11 Is it your opinion as you
12 sit here today, that the 26,000 pharmacy
13 customers that Cardinal Health serves are
14 all approximately the same size?

15 MR. BOGLE: Object to form.

16 THE WITNESS: I did not give
17 an opinion one way or the other on
18 the 26,000 customers that --

19 BY MS. WICHT:

20 Q. Fair.

21 And the definition of
22 suspicious order is the same for all
23 customers, correct?

24 A. The regulatory definition is

1 the same for what constitutes a
2 suspicious order.

3 Q. So, is it your opinion that,
4 as you sit here today, that Cardinal
5 Health should have been able to write a
6 standard operating procedure that
7 provided granularity as to the definition
8 of a suspicious order for 26,000
9 different customers of diverse sizes and
10 types? Is that your opinion?

11 MR. BOGLE: Object to form.

12 THE WITNESS: Could you
13 repeat the question for me?

14 BY MS. WICHT:

15 Q. Sure.

16 Is it your opinion as you
17 sit here today that Cardinal Health
18 should have been able to write a standard
19 operating procedure that provided
20 granularity as to the definition of a
21 suspicious order for 26,000 different
22 customers of diverse sizes and types?

23 MR. BOGLE: Object to form.

24 THE WITNESS: Again, because

1 I think we were trying to discuss,
2 the point here is you can
3 classify, you can group, you can
4 do things to put pharmacies and
5 different pharmacies and different
6 business models into different
7 classes and then set thresholds
8 and other requirements based on
9 that.

10 What I'm saying is, just
11 having an open-ended,
12 significantly larger,
13 significantly greater, those are
14 incredibly imprecise terms. There
15 needs to be more precision around
16 those terms.

17 BY MS. WICHT:

18 Q. Did you review Cardinal
19 Health's policies and procedures to
20 determine whether they did, in fact,
21 group pharmacies by size and business
22 model as part of their suspicious order
23 monitoring system?

24 A. Let me flip through my

1 report. I can tell you.

2 I did.

3 Q. Where are you reading, sir?

4 A. If you happen to look on
5 114, the quote under establishing
6 thresholds.

7 Q. Okay. And that block quote
8 that you just directed me to on Page 114
9 reflects that, as one part of its process
10 to establish threshold limits, Cardinal
11 Health differentiated customers through
12 segmentation by size and/or specialty,
13 correct?

14 A. Yes, that's what I directed
15 you to.

16 Q. Okay. So Cardinal Health
17 did, in fact, group pharmacies by size
18 and specialty as part of their suspicious
19 order monitoring program, correct?

20 MR. BOGLE: Object to form.

21 THE WITNESS: Could you
22 restate the question?

23 BY MS. WICHT:

24 Q. Sure.

1 As part of the processes for
2 its suspicious order monitoring program,
3 Cardinal Health did, in fact,
4 differentiate customers through
5 segmentation by size and/or specialty,
6 correct?

7 A. Well, that's what the SOP
8 says is that's what you are supposed to
9 do.

10 Q. Okay. Dr. Whitelaw, do you
11 have a set of notes related to Cardinal
12 Health that you prepared as part of your
13 deposition prep?

14 A. Yes, I do.

15 Q. Did you review those notes
16 last night or this morning in preparation
17 for your deposition testimony today?

18 A. No, I did not.

19 MS. WICHT: Okay. We've
20 been going about an hour and ten
21 minutes. If we can take a break.

22 MR. BOGLE: Okay.

23 THE VIDEOGRAPHER: Going off
24 the record at 9:41 a.m.

1 (Short break.)

2 THE VIDEOGRAPHER: We are
3 back on the record at 9:57 a.m.

4 BY MS. WICHT:

5 Q. Dr. Whitelaw, I'm going to
6 ask you questions about a few of the
7 specific pharmacies that are identified
8 in your report now.

9 If you would turn to Page
10 51, please.

11 A. You said 51, correct?

12 Q. Yes, sir, Page 51. Your
13 section about CVS Store 3322.

14 Do you see that?

15 A. I do.

16 Q. And in your report you note
17 that Cardinal Health distributed
18 hydrocodone to this CVS location,
19 correct?

20 A. That's what it says in the
21 report, yes.

22 Q. And this CVS Store 3322, as
23 you note, is located on Brookpark Road in
24 Cleveland, Ohio, correct?

1 A. That's the address I had in
2 the documents I saw, yes.

3 Q. Do you know anything about
4 the area surrounding that location, sir?

5 MR. BOGLE: Object to form.

6 THE WITNESS: Could you be
7 more specific?

8 BY MS. WICHT:

9 Q. Have you ever been there?

10 A. No, I have not.

11 Q. Did you look it up on Google
12 Maps as part of your work on this case?

13 A. No, I did not.

14 Q. Are you aware of whether
15 there are any medical centers nearby that
16 CVS location?

17 A. No, I am not.

18 Q. Are you familiar with a
19 Saint Vincent Charity Medical Center
20 nearby that pharmacy?

21 A. No, I am not aware of it.

22 Q. Are you familiar with a
23 Veterans Affairs outpatient clinic that's
24 about ten minutes away from that

1 pharmacy?

2 A. No, I am not.

3 Q. Did you compare the volumes
4 of hydrocodone and oxycodone at CVS 3322
5 that are recited in your report, to
6 volumes of noncontrolled substances that
7 were distributed to that store?

8 A. No, Counselor, I did not.

9 Q. Did you review Cardinal
10 Health's tableau files related to CVS
11 Store 3322?

12 A. No, I did not.

13 Q. Are you aware of there -- of
14 DEA taking any enforcement action against
15 CVS Store 3322?

16 A. I am not aware of that, no.

17 Q. Are you aware of the
18 pharmacy or any of its pharmacists having
19 their license suspended related to
20 controlled substances?

21 A. Counselor, we can go through
22 lots of documents. I looked at lots of
23 documents. This store is offered up for
24 the fact that when I look at the due

1 diligence file from behind this store, I
2 didn't see adequate documentation to
3 explain any of the things, for example,
4 or any of the contributing factors that
5 you were talking about, such as distance
6 from a hospital or geographic location,
7 et cetera. I didn't see that. That was
8 the point that I was making here.

9 Q. You didn't review Cardinal
10 Health's Tableau file, correct?

11 A. No, I did not review
12 Cardinal Health's Tableau file.

13 Q. So you don't know what
14 information about the pharmacy's
15 contained there, correct?

16 A. Again, I reviewed the due
17 diligence files on this -- that I was
18 provided on this particular pharmacy and
19 I didn't see any of the information that
20 you're talking about in the file that I
21 recall.

22 Q. Did you review any Cardinal
23 Health documentation about the thresholds
24 for this particular pharmacy?

1 A. I'm sorry. I'm not sure I'm
2 following your question.

3 Q. Did you review any Cardinal
4 Health documentation about the
5 thresholds, the controlled substance
6 thresholds, that Cardinal Health set for
7 this particular CVS Store 3322?

8 A. Again, if it was in the due
9 diligence file, I reviewed it. If it
10 wasn't in the due diligence file, I did
11 not review it.

12 Q. Do you recall whether it was
13 or wasn't?

14 A. I don't rightly recall.
15 I've looked at -- as I've said I looked
16 at a lot of pharmacies. If you have
17 something in particular that you'd like
18 me to consider, please show it to me.
19 I'm happy to consider it now.

20 Q. So the question I was asking
21 you before, sir, was whether you're aware
22 of CVS Store 3322 or any of the
23 pharmacists who work there having
24 discipline against their licenses related

1 to controlled substance dispensing.

2 A. And I'm going back to my --

3 Q. Are you aware of that?

4 A. I'm going back to my
5 original answer. I reviewed the due
6 diligence file. This pharmacy was
7 offered up in my report as an example of
8 poor due diligence -- documented due
9 diligence. That's why it's here.

10 Q. Sir, respectfully, I'm not
11 asking you what you reviewed. I'm asking
12 you, as you sit here today, whether you
13 are aware of any discipline against CVS
14 Store 3322 or any of its pharmacists in
15 connection with controlled substance
16 dispensing?

17 A. Counselor, as I've said and
18 I tried to be honest and open and
19 transparent with you, I've reviewed a lot
20 of files on a lot of different
21 pharmacies, and no, I don't recall it off
22 the top of my head.

23 Q. Are you offering an opinion
24 that CVS Store 3322, that Cardinal should

1 have cut off distributions to that
2 customer?

3 MR. BOGLE: Object to form.

4 THE WITNESS: As I said, my
5 opinion is limited to the fact
6 that if you looked at the volumes,
7 it should have triggered due
8 diligence. There should be a
9 robust due diligence file. I
10 reviewed the due diligence file
11 that was provided, and I found it
12 to be lacking. That was what I
13 was reviewing.

14 BY MS. WICHT:

15 Q. Based on that answer, and on
16 your report, then, I understand that you
17 are not offering an opinion that Cardinal
18 Health should have cut off distribution
19 of controlled substances to CVS
20 Store 3322, correct?

21 MR. BOGLE: Object to form.

22 THE WITNESS: What I'm
23 offering an opinion to is the
24 adequacy of the due diligence

1 documentation that I was provided
2 and reviewed. And so I can't --
3 because of the documentation that
4 I have, I couldn't give you a
5 recommendation one way or the
6 other on the store.

7 I'm looking for adequate
8 documentation. I don't find it.

9 BY MS. WICHT:

10 Q. Do you -- are you offering
11 the opinion that CVS Store 3322 should
12 have been shut down by the DEA?

13 MR. BOGLE: Object to form.
14 Asked and answered.

15 MS. WICHT: No, I was asking
16 about Cardinal Health's.

17 MR. BOGLE: All right. He's
18 given you --

19 MS. WICHT: I'm asking about
20 DEA now.

21 MR. BOGLE: He's given you
22 the scope of his opinion though.
23 If you ask him essentially the
24 same question phrased a bunch of

1 different ways -- but you can burn
2 your time that way if you want.
3 Go ahead.

4 THE WITNESS: Could I have
5 the question again, please.

6 BY MS. WICHT:

7 Q. Are you offering the opinion
8 that CVS Store 3322 should have been shut
9 down by the DEA?

10 A. Well, for one thing, I don't
11 purport to speak for the DEA at all in my
12 report. It's not in the scope of my
13 review. And that is not what we were
14 covering here. Again, we were covering
15 the adequacy of the due diligence file
16 that Cardinal was responsible for and
17 that I reviewed.

18 Q. So I want to turn to CVS
19 Store 4800 on the next page, please.

20 A. Sure.

21 Q. And this store is located at
22 590 East Market Street in Akron, Ohio,
23 correct?

24 A. That is the -- what I

1 learned from the files, yes.

2 Q. Have you ever been to that
3 location, sir?

4 A. I have not been to Akron,
5 no. I haven't had the pleasure.

6 Q. Are you aware of whether
7 there are any medical centers nearby CVS
8 Store 4800?

9 A. No, I am not. But again,
10 we're talking about the adequacy of the
11 due diligence file that was on record.
12 And what I reviewed was in your due
13 diligence files that were provided to me.

14 Q. Are you familiar with Summa
15 Rehab Hospital located across the street
16 from that CVS location?

17 A. I do not rightly recall it.
18 But again, if it was in the due diligence
19 file, I'm sure I saw it.

20 Q. Are you familiar with Akron
21 City Hospital, three -- excuse me, three
22 minutes from the location of CVS Store
23 4800?

24 A. Again, if it was in the due

1 diligence file, I would have reviewed it.

2 Q. Are you familiar with the
3 Summa Health Emergency Department that's
4 four minutes from that CVS location?

5 A. Again, if it was in the due
6 diligence file, I would have reviewed it.

7 Q. So the due diligence files
8 that you're referring to for CVS 4800 and
9 CVS 3322, those were provided to you by
10 the plaintiff attorneys, correct?

11 A. At my request.

12 Q. At your request.
13 Understood. Did you review anything
14 outside of the due diligence file about
15 those two customers?

16 A. I have reviewed a lot of
17 documents, Counselor. I can't rightly
18 tell you what all I did. I reviewed lots
19 of documents.

20 Q. What can you name for me, as
21 you sit here today, having billed
22 1,200 hours to this case in the last 6
23 months, what can you name for me here
24 today that you reviewed about CVS 4800 or

1 CVS 3322 outside of the due diligence
2 files?

3 A. Counselor, I looked at a lot
4 of paper. I can't tell you a specific
5 document off the top of my head without
6 reviewing the report. But if you'd like
7 to walk through the report and all the
8 citations, we can do that.

9 Q. Okay. Well, that was going
10 to be my next question, sir.

11 Fair to say that anything
12 you relied on, you would have cited in
13 the report, correct?

14 MR. BOGLE: Object to form.

15 THE WITNESS: Fair to say
16 that I would have -- it would be
17 in the report.

18 BY MS. WICHT:

19 Q. And the question of whether
20 Cardinal Health should have ceased
21 controlled substances distributions to
22 CVS Store 4800, I take it your answer, as
23 it was for the other location, was going
24 to be that was outside the scope of your

1 review, correct?

2 A. Again, I was not making an
3 opinion on whether or not Cardinal should
4 have terminated the store or ceased
5 distribution to the store. What I was
6 discussing was the due diligence
7 activities about this particular store.

8 Q. Okay. There's a couple more
9 pharmacies discussed in your report. If
10 you turn to Page 102, please.

11 A. Sure.

12 Q. Do you see there's a
13 discussion there of a CareMed Pharmacy?

14 A. I'm getting there. I see
15 it.

16 Q. That pharmacy is in Florida,
17 correct, sir?

18 A. That is correct.

19 Q. Do you have any knowledge of
20 any individual in Summit County or
21 Cuyahoga County, Ohio, obtaining opioids
22 that Cardinal Health distributed to
23 CareMed Pharmacy?

24 A. No, Counselor, I don't. But

1 again your program was a national
2 program. You did --

3 Q. I -- you answered my
4 question, sir.

5 MR. BOGLE: You can -- you
6 can finish your answer.

7 THE WITNESS: You were --
8 the program I looked at was on a
9 national basis, so it involved
10 pharmacies from all over the
11 country. Therefore, how you
12 treated and followed your policies
13 or didn't follow your policies is
14 relevant to this discussion for
15 Summit and Cuyahoga County. But
16 it's relevant to how you ran your
17 program.

18 And in this case I found the
19 program lacking, because you
20 had -- where you did have policies
21 they were unclear. And where you
22 had -- and on a number of
23 occasions, you didn't follow them.

24 BY MS. WICHT:

1 Q. Sir, my question had nothing
2 to do with policies. Nothing to do with
3 policies.

4 I have very limited time.
5 I'm going to ask you again to please
6 answer the questions that I ask.

7 If you turn to Page 103 --

8 A. I am trying to answer your
9 question.

10 Q. -- there is a pharmacy
11 CVS 219 that's discussed in your report,
12 correct?

13 A. I see CVS Pharmacy 219.

14 Q. And that pharmacy is located
15 in Florida, correct?

16 A. That pharmacy is located in
17 Florida.

18 Q. And you have no knowledge,
19 sir, of any individual from Summit or
20 Cuyahoga County, Ohio, receiving opioids
21 that Cardinal Health distributed to
22 Pharmacy 219, correct?

23 A. Again, as I've stated to
24 you, these pharmacies are examples of the

1 process and policies and failure to
2 follow those processes and to design an
3 adequate system which you ran on a
4 national basis, they are examples, and
5 that's why they are included in this
6 report.

7 Q. So you didn't actually
8 answer my question at all that time.

9 Is it correct that you have
10 no knowledge of any individual from
11 Summit County or Cuyahoga County, Ohio,
12 receiving opioids that Cardinal Health
13 distributed to pharmacy 2 -- pharmacy
14 CVS 219 in Florida?

15 A. I have no specific knowledge
16 of anybody in Cuyahoga or Summit County
17 receiving product from this particular
18 CVS store.

19 Q. I'm going to ask you a
20 question about regulatory guidance, sir.
21 I think a few times in your testimony
22 you've referred to guidance from DEA in
23 the form of letters or presentations or
24 discussions, correct?

1 Do you recall very generally
2 discussing that guidance?

3 A. Yes, I do.

4 Q. And it's correct, sir, that
5 guidance, regulatory guidance is not law,
6 correct?

7 MR. BOGLE: Object to form.

8 THE WITNESS: It's not
9 statute. It's not regulations,
10 that's true.

11 BY MS. WICHT:

12 Q. So if a registrant does not
13 comply with guidance, the registrant is
14 not breaking the law, correct?

15 MR. BOGLE: Object to form.

16 THE WITNESS: Again, I can't
17 make a judgment one way or the
18 other. I'd have to know more
19 facts and circumstances to be able
20 to opine on that.

21 BY MS. WICHT:

22 Q. Is it your opinion that
23 there is some circumstance in which a
24 failure to comply -- strike that.

1 Guidance does not have the
2 force of law, correct?

3 MR. BOGLE: Object to form.

4 THE WITNESS: I am not here
5 to offer a legal opinion. I'm
6 going to tell you how we use
7 guidance as a compliance officer
8 if you'd like.

9 BY MS. WICHT:

10 Q. No thank you.

11 A. I use guidance as --

12 Q. Sir --

13 A. -- as one way of looking --

14 Q. Sir, I did not ask that
15 question, sir.

16 MR. BOGLE: You can finish
17 your answer.

18 MS. WICHT: He
19 acknowledged --

20 MR. BOGLE: Withdraw the
21 question. Withdraw the question.

22 MS. WICHT: He acknowledged
23 that he was moving on to speak
24 about a different topic. He said,

1 "I'm not here to offer a legal
2 opinion, but I'll be happy to tell
3 you how guidance works for
4 compliance officers if you'd
5 like."

6 That was not the question I
7 asked. I'm moving on.

8 MR. BOGLE: Are you still
9 answering?

10 THE WITNESS: I would still
11 give an answer. Yes.

12 MR. BOGLE: Finish your
13 answer.

14 THE WITNESS: My answer
15 would be, we use guidance as a way
16 of informing us on how to frame
17 out and comply with regulations
18 and statutes.

19 It is useful information, we
20 use it that way.

21 BY MS. WICHT:

22 Q. Does a guidance letter
23 create a legal obligation?

24 MR. BOGLE: Object to form.

1 THE WITNESS: I'm not here
2 to offer a legal opinion one way
3 or the other on guidance
4 documents. I'm here as a
5 compliance expert.

6 But I am going to tell you
7 that if you don't --

8 BY MS. WICHT:

9 Q. Sir, I'd like to talk --

10 A. -- if you don't follow
11 guidance, you are running a risk as a
12 company. That's what I would tell my
13 clients and have told my clients.
14 Guidance is useful and should be at least
15 factored into the decisionmaking process.

16 MS. WICHT: So, Counsel, I'm
17 just putting you on notice right
18 now, that I'm -- I'm going to hold
19 the deposition open -- I'm going
20 to move to strike all the
21 nonresponsive speeches that the
22 witness is giving. I'm going to
23 hold the deposition open. I'm not
24 going to conclude it today,

1 because he's not answering the
2 questions that are posed to him.
3 So I'm putting you on notice of
4 that right now. Let's move on to
5 something else.

6 MS. CASTLES: Join.

7 MS. MONAGHAN: Join.

8 MS. McCLURE: Join.

9 MR. BOGLE: I think he's
10 answering just fine. I think he's
11 answering just fine.

12 BY MS. WICHT:

13 Q. So I'd like to ask you a
14 question about Page 104 of your report,
15 sir. Going back to your discussion of
16 Cardinal Health's corporate culture.

17 A. I'm there.

18 Q. Okay. The first sentence of
19 Section 10.4.1 says, "Cardinal culture
20 was and continues to be myopically
21 focused on increasing revenues and
22 cutting costs."

23 Is that your opinion?

24 A. That is my opinion.

1 Q. Are -- do you know anything
2 about Cardinal Health's program called
3 Generation Rx?

4 A. Not off the top of my head,
5 that I can recall, Counselor.

6 Q. You are not familiar with
7 that drug abuse and misuse prevention
8 program that Cardinal Health created in
9 partnership with the Ohio State
10 University College of Pharmacy?

11 A. Counselor, it was not
12 something I looked at and it was not part
13 of this report, no.

14 Q. Okay. All right. Do you
15 know anything about Cardinal Health's
16 opioid action program?

17 A. No, Counselor, I don't.

18 Q. Okay.

19 A. But if you have something
20 you'd like me to look at, I'd be happy to
21 look at it right now for you.

22 Is there a --

23 Q. You talked in your report
24 generally about the concept of

1 accountability. Do you recall that?

2 A. Yes.

3 Q. Okay. And that refers to
4 accountability for employees who, in your
5 opinion, performed inadequately in their
6 compliance functions, correct?

7 A. I would say that was one
8 facet of it. The other facet of
9 accountability had to do with how you
10 handle customers that don't follow or
11 won't give you documents, won't
12 provide -- provide help, won't follow
13 your procedures and procedures --

14 Q. Okay. So I'm --

15 A. -- or follow contracts. So
16 we're talking about both.

17 Q. I'm focused at the moment on
18 the issue of accountability for
19 employees. Okay?

20 A. Okay.

21 Q. So -- and I think you said
22 yesterday that accountability doesn't
23 necessarily require the termination of
24 an -- of an employee, correct, in your

1 opinion?

2 A. I said accountability, there
3 were a range of options. Termination was
4 a possibility.

5 Q. Okay. And reduction in pay
6 or bonus, that was another possibility
7 that I think you mentioned?

8 A. All fact and circumstance
9 driven.

10 Q. Okay. And transfer to
11 another part of the organization, that
12 was another possible --

13 A. It was possible.

14 Q. Excuse me. Let me finish
15 the question. Thank you.

16 That's another -- excuse me.
17 Lost my train of thought.

18 Transfer to another part of
19 the organization is another possibly way
20 that a company could have accountability
21 for employees, correct?

22 A. It is another possibly way,
23 yes.

24 Q. Okay. You -- on Page 120 of

1 your report, sir, you discuss Cardinal
2 Health --

3 A. Which page are we on?

4 Q. 120, sir.

5 A. Okay. I'm there.

6 Q. You discuss Cardinal Health
7 notifying customers on their invoices
8 that their orders had been held pending
9 regulatory review. Do you recall that?

10 A. Is there a specific
11 paragraph on this page?

12 Q. Top paragraph. No, I'm
13 sorry, the third paragraph on the page.
14 "The customer will see on the invoice
15 held pending regulatory review."

16 Do you see that?

17 A. I do see that.

18 Q. Okay. Do you -- is it your
19 opinion that it was improper for Cardinal
20 to notify its customers that their
21 invoices were being held -- I'm sorry,
22 that their order -- orders were being
23 held pending regulatory review?

24 A. I didn't say it was

1 improper. What I said was it gave
2 customers a way of understanding what
3 their thresholds were without
4 communicating it directly. They could
5 back into the thresholds, and it was
6 something that needed to be factored in
7 and taken into account.

8 Q. I take it it was outside the
9 scope of your work in this case to
10 determine whether any customer actually
11 backed into their thresholds and used
12 that information to work around the
13 thresholds, correct?

14 MR. BOGLE: Object to form.

15 THE WITNESS: Again, I'm
16 speaking to the process.

17 BY MS. WICHT:

18 Q. So I think that's yes,
19 right, it was outside the scope of your
20 work in this case to determine whether
21 that actually happened with any specific
22 customer?

23 A. It was outside of my scope
24 to look at it in the case of a specific

1 customer.

2 Q. Okay. I believe you
3 testified yesterday, sir, but please
4 correct me if I'm wrong, that you did
5 compliance program-related work for a
6 distributor who is named as a defendant
7 in this case; is that correct?

8 A. That was -- again, I have to
9 look at the transcript to remember
10 exactly what I said. But I believe that
11 is correct.

12 Q. Did that work include --
13 strike that.

14 Was that work in your
15 capacity as a consultant at your current
16 company?

17 A. No, it was not.

18 Q. In what capacity did you do
19 that work?

20 A. It would have been when I
21 was working for Deloitte, to the best of
22 my recollection.

23 Q. Okay. Did that work include
24 consulting on the distributor's

1 suspicious order monitoring program?

2 A. Well, again, I'm not sure
3 which distributor we are talking about.
4 Can we be a little more precise?

5 Q. I'm talking about whichever
6 distributor you did work for.

7 A. Well, okay --

8 MR. BOGLE: If we can keep
9 it down over there, please, and be
10 respectful and professional.

11 MS. WICHT: I just -- let
12 the record reflect that the
13 witness is smiling as well. I --
14 nobody was --

15 THE WITNESS: I'm trying to
16 understand --

17 MR. BOGLE: It was on video.
18 You don't need to have the record
19 reflect anything.

20 MS. WICHT: I agree. It
21 will reflect that he was smiling.

22 MR. BOGLE: Whether he's
23 smiling has nothing to do with
24 whether 20 people are laughing out

1 loud while you're asking
2 questions.

3 BY MS. WICHT:

4 Q. The compliance
5 program-related work that you did for a
6 distributor who is named as a defendant
7 in this case, did it include consulting
8 with respect to that distributor's
9 suspicious order monitoring program?

10 A. To the best of my
11 recollection, Counselor, no it did not.

12 Q. Okay. And if you look at
13 Page 2 in your report, the second
14 paragraph on that page says, "None of the
15 organizations reviewed in this report
16 have employed me or engaged the services
17 of me and my firm." And my question is,
18 is that a true statement?

19 A. Yes, I believe it is a true
20 statement.

21 Q. Okay. Yesterday at one
22 point during your testimony, you referred
23 to the fact that you were working for the
24 court. Do you recall saying that?

1 A. I do recall saying that.

2 Q. So I want to be clear about
3 that, sir. You haven't been engaged by
4 the court to serve as an expert in this
5 case, correct?

6 A. No, I have not.

7 Q. You are engaged by plaintiff
8 attorneys, correct?

9 A. That is correct.

10 Q. And it's not the court who
11 owes you about \$480,000 at this point,
12 correct? It's the plaintiff attorneys,
13 correct?

14 A. That is correct. However, I
15 feel that I have an obligation to the
16 court to do the very best work that I
17 can, because it's not just plaintiffs'
18 counsel that's reading it. You're
19 reading it. The judge is going to be
20 reading my report. So, therefore, I
21 believe that there's an obligation to do
22 the very best work possible.

23 Q. How much of your current
24 business is consulting for plaintiffs in

1 this case?

2 A. I don't rightly know off the
3 top of my head.

4 Q. Do you have other work
5 currently?

6 A. Yeah, I do currently.

7 Q. Okay. Would you say that
8 your consulting work for plaintiffs in
9 this case is more than 50 percent of your
10 current work?

11 MR. BOGLE: Object to form.
12 Asked and answered.

13 THE WITNESS: As I said,
14 Counselor, I don't have a precise
15 number for you.

16 BY MS. WICHT:

17 Q. So you're the -- are you the
18 sole employee of your business?

19 A. Yes, Counselor, I am.

20 Q. So you -- you manage it, you
21 operate it, you do everything with
22 respect to the business, correct?

23 A. I do.

24 Q. And you, as you sit here

1 today, cannot tell me what percentage of
2 your current business approximately is
3 consulting for plaintiffs in this case,
4 correct?

5 MR. BOGLE: Objection.

6 Asked and answered.

7 THE WITNESS: Counselor, I
8 can't.

9 MS. WICHT: Okay. I have
10 many, many more lines of
11 questioning that I have not had
12 time to get into today both
13 because of the time constraints of
14 the deposition, and because of
15 respectfully, in my opinion, the
16 answers that the witness has
17 provided. In deference to my
18 colleagues, who are on the defense
19 side I'm going to pass the witness
20 now. But I have more examination
21 to do, and I am going to hold the
22 deposition open and reserve the
23 right to seek more time or other
24 relief. If we can go off the

1 record in order to hand over the
2 mic please.

3 THE VIDEOGRAPHER: Going off
4 the record at 10:23 a.m.

5 (Brief pause.)

6 THE VIDEOGRAPHER: We are
7 back on record at 10:29 a.m.

8 - - -

9 EXAMINATION

10 - - -

11 BY MR. MELTON:

12 Q. Good morning, Dr. Whitelaw.

13 A. Good morning.

14 Q. My name is Jeffrey Melton,
15 and I represent AmerisourceBergen Drug
16 Corporation.

17 A. Nice to meet you.

18 Q. Nice to meet you as well.

19 Before we really get started
20 I wanted to follow up on one question
21 that Ms. Wicht was asking you about her
22 line of questions.

23 A. Sure.

24 Q. I thought I heard you

1 testify yesterday that the compliance
2 work that you had done for a defendant in
3 this case, I thought I heard you say that
4 it was ABC. Did I hear that correctly
5 yesterday?

6 A. No, I don't think you did.
7 I'm not sure I said a defendant.

8 Q. Okay. Is it possible that
9 if I heard ABC, it was, you know, ABC,
10 meaning a string of letters and not ABC
11 meaning AmerisourceBergen Corporation?

12 A. Again, I don't recall --
13 without going back and looking at the
14 testimony, I don't remember. But I don't
15 recall saying I worked for a particular
16 client. I think I was giving a series of
17 clients as examples of clients that
18 Deloitte served. But I don't think I was
19 naming a specific client.

20 Q. So it was not your intention
21 to name ABC?

22 A. It was not my intention. If
23 you heard that that way, that was not my
24 intention.

1 Q. Have you ever done any work
2 for AmerisourceBergen?

3 A. Not that I can recall, no.

4 Q. Is AmerisourceBergen one of
5 the companies that's evaluated in your
6 report that's marked as Exhibit 2?

7 A. Yes, it is.

8 Q. Is there a -- do you recall
9 whether there is a review time period for
10 the AmerisourceBergen section?

11 A. Not off the top of my head.
12 But I can go and flip to the section and
13 look if you'd like.

14 Q. That's okay. We'll get to
15 it.

16 A. Okay.

17 Q. Did you review any documents
18 that informed your opinion on ABC that
19 you did not cite to in your report?

20 A. I looked at a lot of
21 documents. If I used it to support the
22 positions that I -- it was in, it would
23 have been in the report. But I can't
24 rule out, I've looked at a lot of

1 documents -- you know, I've looked at a
2 lot of documents.

3 Q. Did you review any documents
4 that informed your opinion on ABC that
5 you did not list --

6 A. Not to the best of my --

7 MR. BOGLE: Wait until he
8 finishes.

9 THE WITNESS: I'm sorry.

10 Can you ask the question again?

11 BY MR. MELTON:

12 Q. Sure.

13 A. I didn't mean to interrupt
14 you.

15 Q. Did you review any documents
16 that informed your opinion on ABC that
17 you did not list as reliance materials in
18 your report?

19 A. Not that I can recall, sir.

20 Q. Okay. Let's -- let's take a
21 look at Page 126 of your report that's
22 marked as Exhibit 2.

23 A. 126.

24 Okay.

1 Q. And this is the start of the
2 ABC section of your report, correct?

3 A. Mm-hmm, yes, it is.

4 Q. Okay. Can you flip to
5 Page 128?

6 A. I'm there.

7 Q. Okay. Now, on Page 128
8 approximately, it's -- it's in the third
9 paragraph, you use the phrase "bare
10 minimums," do you see that?

11 A. Yeah, I saw it.

12 Q. What do you mean by bare
13 minimums?

14 A. What I mean by bare
15 minimums, where you were doing just
16 enough, or trying to set up a program
17 that went just -- was just barely
18 effective. So you were doing the bare
19 minimums of what you needed to do. You
20 weren't trying to stand -- ABC was not
21 trying to stand out as a stellar
22 performer. They were just doing the
23 basics that they had to do to get by.
24 That's what I meant.

1 Q. So the minimum to meet the
2 regulations, but nothing more, is that
3 your testimony?

4 MR. BOGLE: Object to form.

5 THE WITNESS: The minimums
6 to meet your obligations and
7 nothing more.

8 BY MR. MELTON:

9 Q. Now, yesterday we talked a
10 lot about your chart that's on Page 43 of
11 your report.

12 A. I'm there.

13 Q. Where is the bare minimum
14 located on this chart, if you can tell
15 me?

16 A. The words "bare minimum" are
17 not on the chart.

18 Q. So from -- from left to
19 right on the chart, if you had to place
20 the bare minimum into one of the four
21 categories, where would it be?

22 A. Left, in the foundational.

23 Q. All right. Let's flip to
24 Page 129 of your report.

1 A. I think I'm there.

2 Q. Now, do you see the last
3 sentence before it says Clark Lowcost
4 Pharmacy, where it says, "Below are just
5 a few examples illustrating how ABC's
6 approach to its anti-diversion program
7 translated into various retail pharmacy
8 stores obtaining high levels of opioids
9 with little or no investigation or
10 interrogation."

11 Did I read that correctly?

12 A. Yes, you did read that
13 correctly.

14 Q. Clark Lowcost Pharmacy is
15 one such example?

16 A. Clark Lowcost Pharmacy was
17 one of the examples in the report, yes.

18 Q. And on the next page, on
19 Page 130, Church Square Pharmacy is
20 identified?

21 A. Yes.

22 Q. And is Church Square
23 Pharmacy a second example?

24 A. Yes, it is.

1 Q. Would you define two
2 customer examples as various retail
3 pharmacy stores as quoted from the
4 sentence just before Clark Lowcost
5 Pharmacy?

6 MR. BOGLE: Object to form.

7 THE WITNESS: I believe they
8 are retail pharmacies, yes.

9 BY MR. MELTON:

10 Q. Is it your opinion that two
11 examples of retail pharmacies would form
12 a pattern?

13 A. I'm saying I cited two
14 examples in my report. I think you can
15 start to see the pattern. I think there
16 is a pattern here.

17 Q. With two pharmacies there's
18 a pattern, that's what you're telling me?

19 A. I cited two pharmacies as
20 examples. There are other examples
21 potentially. But I'm saying, if -- if
22 you look, they are illustrative of the
23 issues discussed further on in the
24 report.

1 Q. Did you identify any other
2 examples of pharmacies in your report for
3 ABC?

4 A. We can go through the whole
5 section, but the only two I remember are
6 these two off -- you know, in the
7 front-end. But again I can go through my
8 whole report if you'd like.

9 Q. That's okay.
10 Did you identify these
11 pharmacies yourself?

12 A. Yes, actually I did identify
13 both of these pharmacies myself. Again,
14 I asked counsel, as I testified to
15 yesterday, for pharmacies in Summit and
16 Cuyahoga County. I went through various
17 files and I picked these two as
18 illustrative examples.

19 Q. But you didn't say to
20 counsel, please give me the file for
21 Clark Lowcost Pharmacy, did you?

22 A. I asked counsel to give me
23 files for pharmacies in Cuyahoga and
24 Summit Counties that had high indications

1 of opioid usage, serviced by ABC, as I
2 did for the other defendants as well.

3 Q. Other than Clark Lowcost
4 Pharmacy and Church Square Pharmacy
5 identified in your report, do you intend
6 to offer any opinions for other ABC
7 customers as examples of retail pharmacy
8 stores obtaining high levels of opioids
9 without investigation or interrogation?

10 A. At this point in time
11 without new evidence or facts to be
12 considered, as again as I've said before,
13 I hold my report open to reflecting new
14 information. At this point in time I
15 have no intention.

16 Q. What do you mean by the term
17 "interrogation"?

18 A. What I meant by is asking
19 the question why and trying to find the
20 answer as to why. These are high levels
21 of opioid usage and I didn't see an
22 adequate interrogation as in why is this
23 happening. There's not -- the
24 documentation was not solid enough for me

1 to make a determination that there was a
2 close examination in an attempt to answer
3 the question why. That to me is
4 interrogation.

5 Q. Is Clark Lowcost Pharmacy
6 located in Cuyahoga County?

7 A. According to my report, yes,
8 it is.

9 Q. And also according to your
10 report, ABC completed a threshold review
11 request for this pharmacy in
12 October 2010; is that correct?

13 A. Yes. I saw it.

14 Q. And the threshold review
15 request was submitted by Ron Kline,
16 correct?

17 A. Yeah. That's what the
18 report says.

19 Q. Have you ever spoken to
20 Mr. Kline?

21 A. No, I have not spoken
22 directly to Mr. Kline.

23 Q. Have you ever read any
24 testimony from Mr. Kline?

1 A. Well, let's go back to the
2 reliance list. We can go down my
3 deposition list. So I'd -- I'd have to
4 look there to be able to tell -- answer
5 your question. So if you can give me a
6 minute.

7 Q. If I told you he was not
8 deposed in this case --

9 A. I'd still like to check my
10 own records if you don't mind.

11 Q. Sure. It's 276 is where it
12 starts.

13 A. I know. I'm just trying to
14 flip to the page. I don't see it on the
15 list.

16 Q. Did you interview anyone at
17 ABC regarding this threshold request for
18 Clark Lowcost Pharmacy?

19 A. No, I did not approach
20 anyone at ABC directly, no.

21 Q. Did you review ABC's
22 transactional data for Clark Lowcost
23 Pharmacy?

24 A. Again, if I reviewed it, and

1 it was in the file, I would have reviewed
2 it. I can't tell you off the top of my
3 head other than what's in the report.

4 Q. Okay. I'll represent to you
5 that I did not see a reference to ABC
6 transactional data in -- in your report.
7 Did you review ABC's --

8 A. Well, again, I think it
9 depends on, Counselor, what we're talking
10 about. I mean, I would need your help
11 here to understand what you mean by
12 transactional data, because I would say
13 looking at threshold allotments and
14 actual threshold amounts, that is
15 arguably transactional data. So I'm not
16 sure what you mean by transactional data.

17 Q. Line-by-line sales data.

18 A. Not that I recall.

19 Q. Okay. Did you review ABC's
20 Tableau files that were produced in this
21 case?

22 A. Again, not to my -- I don't
23 have a recollection of it.

24 Q. Now, looking at Page 129.

1 Do you see, sort of in the middle of the
2 page, where there's a one, two and three
3 listed?

4 A. I'm sorry, 129, you said?

5 Q. Yep.

6 A. Yes, I do.

7 Q. Is it your opinion that a
8 customer located within several miles of
9 two hospitals is a red flag?

10 A. I'm not saying it's a red
11 flag. What I'm saying is it's something
12 to be -- it's a factor to be considered
13 looking at how you're setting thresholds.
14 It's information.

15 Q. Is it also a factor to be
16 considered that a customer is located
17 within several miles of a hospital with a
18 pain clinic?

19 A. Again, pain clinics are --
20 have been considered red flags by the DEA
21 in this whole, you know, in Florida and
22 other places. So it is something -- it
23 is another factor to factor in. It is
24 certainly something to explore.

1 Q. What is the basis of your
2 statement that pain clinics have been
3 identified as red flags by the DEA?

4 A. I'd have to go back and pull
5 the front of the report and go through
6 the guidance. But I remember it being
7 guidance. I don't have an exact
8 reference for you.

9 Q. So your testimony is that
10 somewhere in your report --

11 A. My testimony is, I believe,
12 somewhere in the front of the report
13 where we talk about DEA guidance, there
14 is an indicia of diversion. And I
15 believe it's in the Rannazzisi letters.
16 But don't ask me to go farther and tell
17 you which date unless you want me to
18 spend some time -- your time looking it
19 up.

20 Q. No, that's okay. Do you
21 recall yesterday testifying that you
22 spoke to Mr. Rafalski, an expert in this
23 case?

24 A. I do.

1 Q. Did you speak to
2 Mr. Rafalski about red flags?

3 A. I may have. I can't rightly
4 recall whether we spoke -- I'm sure we
5 did speak about it.

6 Q. What do you recall about
7 that conversation?

8 A. I recall that we sort of
9 talked about red flags in general. I
10 think pain clinics were one of the things
11 that he brought -- we discussed. I'm --
12 beyond that. I can't recall. I cannot
13 recall the exact substance of that
14 conversation.

15 Q. But it's your testimony that
16 Mr. Rafalski told you that pain clinics
17 are a red flag?

18 MR. BOGLE: Object to form.

19 THE WITNESS: I'm -- no, my
20 testimony is I believe we
21 discussed pain clinics as a red
22 flag.

23 I can't go any further than
24 that, because I don't rightly

1 recall all the details of that
2 conversation.

3 BY MR. MELTON:

4 Q. Is a customer that's located
5 close to a family practice with a pain
6 clinic also a red flag?

7 A. Again, I think it's
8 something that you need to look at. When
9 I say red flag, it's something that
10 raises -- it requires some additional
11 investigation and due diligence. That's
12 what I'm talking about when I mean red
13 flag.

14 Q. Have you ever heard of a
15 company called the Pharma Compliance
16 Group?

17 A. Yes, I know the Pharma
18 Compliance Group. Why?

19 Q. Are you aware that the
20 Pharma Compliance Group conducts site
21 visits for AmerisourceBergen?

22 A. No, Counselor, I wasn't.

23 Q. Are you aware that the
24 Pharma Compliance Group conducted a site

1 visit of Clark Lowcost Pharmacy on behalf
2 of AmerisourceBergen?

3 MR. BOGLE: Object to form.
4 Vague and ambiguous.

5 THE WITNESS: Can you give
6 me more specifics? Because I
7 looked at a lot of documents. I
8 don't recall that in a document
9 that I saw in what I reviewed.
10 But if you have -- and, again, if
11 you have something that you'd like
12 me to review now, I'm more than
13 happy to take a look at it for
14 you.

15 BY MR. MELTON:

16 Q. So if you did rely on a
17 Pharma Compliance Site visit report, it
18 would be noted as a footnote or in the
19 reliance material in your report,
20 correct?

21 A. It would be noted in --
22 certainly in the reliance materials
23 and/or footnote, yes.

24 Q. Now --

1 A. Again, if you have a
2 document that you'd like me to consider
3 and look at and talk about, I'm more than
4 happy to do that if you have it.

5 Q. No, that's okay. On Page
6 130, if you can flip to Page 130 where it
7 says "Church Square Pharmacy." Church
8 Square Pharmacy is also located in
9 Cuyahoga County; is that correct?

10 A. That is correct.

11 Q. And ABC also completed a
12 threshold review for Church Square
13 Pharmacy?

14 A. I see that, yes.

15 Q. And it's the same Ron Kline
16 who submitted the form, correct?

17 A. I believe that it is
18 correct.

19 Q. Do you know how many
20 customers ABC services in Cuyahoga
21 County?

22 A. Not off the top of my head,
23 Counselor. I can go back and look at my
24 report to see if it's in there.

1 Q. Was this information that
2 you requested?

3 A. Counselor, I requested a lot
4 of information. I'm sure I did request a
5 number of -- of customers. Honestly, I
6 can't tell you precisely every list of
7 requests that I made from counsel. So
8 I'm sorry.

9 Q. Have you identified any ABC
10 customers in Summit County that are
11 examples of retail pharmacy stores
12 obtaining high levels of opioids without
13 investigation or interrogation?

14 A. Again, Counselor, I can't
15 tell you because I don't remember all the
16 pharmacies that I looked at.

17 Q. But if you -- if you had
18 identified a customer in Summit County,
19 it would be noted in your report,
20 correct?

21 A. It might have been. Again,
22 I was looking for examples. I picked
23 some examples, illustrative, just like
24 you do in an audit. I can't tell you

1 without more precision and looking at
2 individual pharmacies whether it would
3 have made it into the report or not.
4 So...

5 Q. I'll back up to Clark
6 Lowcost Pharmacy just for one second. Do
7 Pages 129 -- the section begins on page
8 129 and goes to 130.

9 A. Correct.

10 Q. Are Pages 129 and 130 --
11 strike that.

12 Do Pages 129 and 130 contain
13 all of the opinions that you intend to
14 offer regarding Clark Lowcost Pharmacy?

15 A. Again, as we discussed
16 previously, unless there is new
17 information that comes to light that
18 warrants a review, at this moment in time
19 I believe I will be offering no more
20 opinions on these -- on this pharmacy.

21 Q. Same question about Church
22 Square Pharmacy. Does page -- do Pages
23 130 and 131 contain all of the opinions
24 that you intend to offer regarding Church

1 Square Pharmacy?

2 A. Again, unless anything new
3 comes to light that warrants me to
4 revisit it as per my report, as I state
5 upfront, it is my intention at this
6 moment not to add anything to the report
7 on this issue.

8 Q. Do you intend to add
9 anything to the report for Summit County
10 customers?

11 A. Again, unless I had
12 something -- again, as I said, I will
13 supplement this report as important new
14 data comes forward. It is not my
15 intention at this point to supplement my
16 report.

17 Q. All right. Now I want to
18 ask you some questions about
19 AmerisourceBergen's order monitoring
20 program. And let's take a look at Page
21 138 of your report.

22 A. Okay. I'm there.

23 Q. Do you see where it says
24 11.5.1, "Prior to 2007

1 AmerisourceBergen's two-part controlled
2 substance program was at best rudimentary
3 and not compliant with DEA regulatory
4 requirements"?

5 A. Yes, I see that.

6 Q. Is the time period covered
7 by this section prior to 2007, does that
8 mean 1997 to 2007?

9 A. Well, we have to go to the
10 front of the report, what we said at the
11 start of the period was --

12 Q. I think you can look in the
13 second paragraph of this section.

14 A. Okay. I would say 1997 to
15 2007 is accurate counselor.

16 Q. And during that time period,
17 1997 to 2007, the DEA had the authority
18 to inspect AmerisourceBergen's
19 distribution centers, correct?

20 A. Yes. They did have that
21 authority.

22 Q. Was the DEA in the best
23 position to determine whether ABC was
24 compliant with DEA's regulatory

1 requirements?

2 MR. BOGLE: Object to form.

3 THE WITNESS: No, Counselor,
4 you were in the best -- ABC was in
5 the best position to determine
6 whether it was compliant with the
7 regulations. The onus is on the
8 registrant to be in compliance
9 with the regulations.

10 BY MR. MELTON:

11 Q. And which regulatory
12 requirements are you referring to?

13 A. The Controlled Substances
14 Act, controlled substances regulatory
15 regulations.

16 Q. Now, I noticed in the
17 section that Footnotes 737 738, 740, 741,
18 742, and 743 all refer to the Chris
19 Zimmerman deposition transcript; is that
20 correct?

21 A. They all refer to that
22 deposition transcript, yes.

23 Q. You've reviewed Chris
24 Zimmerman's deposition transcript in

1 preparing your report?

2 A. I did review Chris
3 Zimmerman's deposition transcript in
4 preparing this report.

5 Q. Did you review the
6 deposition transcript in its entirety?

7 A. I believe I did. I'm pretty
8 sure I read the whole thing. But, again,
9 I read a lot of depositions, so I can't
10 be absolutely certain.

11 Q. Are you aware that
12 Mr. Zimmerman testified that he was part
13 of the DEA's suspicious order task force
14 in 1998?

15 A. I vaguely recall him saying
16 something like that in his deposition,
17 yes.

18 Q. Are you aware that
19 Mr. Zimmerman testified that ABC
20 implemented a suspicious order monitoring
21 program in 1998 working with DEA?

22 MR. BOGLE: Object to form.

23 THE WITNESS: I do -- again
24 have a general recollection of

1 that. Again, if there's specific
2 statements that you'd like me to
3 look at in his deposition, I'm
4 happy to look at them now to
5 refresh my recollection.

6 BY MR. MELTON:

7 Q. But as you sit here today,
8 you have a general recollection but could
9 not tell me one way or the other unless
10 you reviewed Mr. Zimmerman's transcript?

11 A. Well, again, to be precise,
12 you're asking me to be incredibly
13 precise. I would need to see the
14 document to be incredibly precise. To
15 the best of my knowledge and
16 recollection, I do recall something in
17 his deposition to that effect.

18 Q. Are you aware that
19 Mr. Zimmerman testified that ABC
20 implemented a suspicious order monitoring
21 program in 1998 that was approved by the
22 DEA?

23 MR. BOGLE: Object to form.

24 THE WITNESS: Again, I don't

1 recall that off the top of my
2 head. Do you have -- again, do
3 you have something in particular
4 that you'd like me to look at?

5 BY MR. MELTON:

6 Q. Whether ABC had a suspicious
7 order monitoring program that was
8 approved by the DEA, would that
9 information be germane to your evaluation
10 of ABC's compliance program?

11 A. Can you give me the question
12 again, please, Counselor?

13 Q. Whether ABC had a suspicious
14 order monitoring program that was
15 approved by the DEA as Mr. Zimmerman
16 testified, would that information be
17 germane to your evaluation of ABC's
18 program prior to 2007?

19 A. It would certainly be
20 information that I would consider, but I
21 don't see how it would affect the
22 opinions that I've rendered in this case.

23 Q. Let's go back to Page 132 of
24 your report.

1 A. I'm here.

2 Q. So in the second full
3 paragraph in the middle, do you see where
4 it says "however"? And the statement
5 reads, "However, the DEA was not
6 obligated to participate in or provide
7 input on ABC's program and doing so would
8 have run contrary to the DEA's
9 long-standing position that it does not
10 endorse particular systems or programs."

11 A. I see that.

12 Q. Now, I note that there's no
13 citation provided for that statement.
14 What is the basis for that statement?

15 A. Again, I'd have to go to the
16 front of the report and go find you the
17 exact citations to the controlled
18 substances guidance. But we can page
19 through the report if you'd like,
20 Counsel.

21 Q. But you would agree that
22 there's no citation to this statement --
23 this section.

24 A. I would agree --

1 MR. BOGLE: Wait until he
2 finishes.

3 THE WITNESS: Sorry.

4 BY MR. MELTON:

5 Q. You would agree that there's
6 no citation to anything for this
7 statement?

8 A. I would agree there's no
9 footnote here.

10 Q. Did you speak to
11 Mr. Rafalski about this topic?

12 A. I may have. Again, as I
13 told you I don't have a detailed
14 recollection of my conversations on all
15 topics with Mr. Rafalski. We talked
16 about a lot of different topics, DEA
17 internal. But I do believe we had that
18 conversation.

19 Q. You also reviewed the
20 deposition transcript of Steve Mays in
21 preparing your report; is that correct?

22 A. Yes.

23 Q. Did you review the entire
24 transcript for Mr. Mays?

1 A. Again, Counselor, I don't
2 remember whether I reviewed the full
3 transcript or not. I can't tell you.

4 Q. Are you aware that Mr. Mays
5 testified that ABC worked closely with
6 the DEA to develop enhancements to its
7 program in 2007?

8 MR. BOGLE: Object to form.

9 THE WITNESS: Again
10 Counselor, generically, yes. Do I
11 recall a specific reference? No.

12 BY MR. MELTON:

13 Q. Now, you also reviewed the
14 settlement agreement entered into between
15 ABDC and the DEA in 2007 in formulating
16 your report, correct?

17 A. I did.

18 Q. Would you agree that ABDC is
19 obligated to comply with the terms of the
20 2007 settlement agreement?

21 A. May I see the document again
22 to refresh my recollection again? You're
23 asking me specific questions about
24 specific documents, and I reviewed a lot

1 of documents. It would be helpful to see
2 the document.

3 Q. We'll get there. Just more
4 generically, would you agree that the
5 parties to an agreement are bound by that
6 agreement?

7 A. Again, I would agree that
8 parties sign an agreement, it's like a
9 contract if that's what you're asking,
10 Counselor. Again, I'm not sure what
11 you're asking.

12 Q. And so if there is a
13 contract, the parties are bound by that
14 contract?

15 A. That's usually the way we do
16 business.

17 (Document marked for
18 identification as Exhibit
19 Whitelaw-17.)

20 BY MR. MELTON:

21 Q. So I've marked the 2007
22 settlement agreement as Exhibit Number
23 17.

24 A. Okay.

1 Q. The document is Bates
2 labeled ABDCMDL 00279854 to 865. You can
3 take a minute and familiarize yourself
4 with that.

5 A. Sure. Thank you. I see it.

6 Q. So I'd like to direct your
7 attention to Page 2 of the document where
8 it says, "Obligations of
9 AmerisourceBergen."

10 A. I see it.

11 Q. Do you see paragraph little
12 (a), where it says, "AmerisourceBergen
13 agrees to maintain a compliance program
14 designed to detect and prevent diversion
15 of controlled substances which shall
16 apply to the Orlando facility and all
17 other existing and future distribution
18 centers of AmerisourceBergen in the
19 United States"?

20 Do you see that?

21 A. Yes, I see that section.

22 Q. And then at the bottom of
23 Page 2, moving onto Page 3, Subsection C,
24 where it says, "Any material breach of

1 subsections Roman numeral II(1)(a) or (b)
2 of this agreement by AmerisourceBergen
3 after DEA restores the Orlando facility's
4 registration, may be a basis upon which
5 DEA can issue an order to show cause
6 seeking the revocation of the DEA
7 certificate of registration associated
8 with the distribution center whose
9 conduct is related to the material breach
10 of the agreement."

11 Do you see that?

12 A. I do see that.

13 Q. Aside from this 2007 issue
14 with the DEA, has AmerisourceBergen been
15 the subject of a second enforcement
16 action by the DEA?

17 A. Not to the best of my
18 knowledge, it has not.

19 Q. Has AmerisourceBergen paid
20 any fines relating to the diversion of
21 controlled substances after 2007?

22 A. Again, not to the best of my
23 knowledge.

24 Q. Are you aware that

1 AmerisourceBergen didn't pay a fine in
2 2007 either?

3 A. Yes, I am aware of that.

4 Q. Now, on Page 3 of the
5 document, where it says, "Obligations of
6 DEA"?

7 A. Yep.

8 Q. Do you see that?

9 A. I do see that.

10 Q. And Subsection A where it
11 says, "The DEA shall continue to provide
12 diversion, prevention, and awareness
13 training as practicable to retail
14 pharmacy and industry members at
15 AmerisourceBergen trade shows and through
16 written materials"?

17 A. I see it.

18 Q. So the DEA was obligated by
19 this agreement to provide diversion
20 prevention and awareness training at ABC
21 trade shows; is that correct?

22 A. That's what it states on the
23 face of the document, yes.

24 Q. Moving onto Subsection C.

1 Do you see where it says, "The DEA shall
2 conduct reviews of the functionality of
3 AmerisourceBergen's diversion compliance
4 program at up to five distribution
5 centers of AmerisourceBergen"?

6 A. Yes, I do see the -- I see
7 what you're reading from, yes.

8 Q. So AmerisourceBergen had to
9 pass functionality reviews by the DEA to
10 get their immediate suspension order
11 lifted; is that correct?

12 MR. BOGLE: Object to form.

13 THE WITNESS: What I see
14 here is simply a statement that
15 they shall conduct reviews of
16 functionality at up to five
17 distribution centers. That's all
18 I see here.

19 BY MR. MELTON:

20 Q. So DEA reviewed
21 AmerisourceBergen's program at up to five
22 distribution centers, is that fair?

23 MR. BOGLE: Object to form.

24 THE WITNESS: I can't

1 comment on whether they did or did
2 not review them. I'm saying that
3 this was -- well, there was an
4 obligation that reads just like we
5 read the sentence back, in this
6 document. That's all I can state
7 to.

8 The document says what you
9 say it says.

10 BY MR. MELTON:

11 Q. On Pages 4 and 5 of the
12 document, do you see the section titled
13 "Joint Obligations of the Parties"?

14 A. Hang on a second. I see
15 Section 3, "Joint Obligation of Parties,"
16 yes.

17 Q. And in that section,
18 Subsection B where it says, "DEA and
19 AmerisourceBergen shall meet no less than
20 annually at DEA headquarters to discuss,
21 rely, suggestions for improvements at
22 AmerisourceBergen's compliance program to
23 detect and prevent diversion of
24 controlled substances; two, any concerns

1 of the DEA related to the sales pattern
2 of controlled substances by
3 AmerisourceBergen; and three, any other
4 issues of concern to either party."

5 Do you see that?

6 A. I do see that.

7 Q. So according to this
8 section, DEA was obligated to provide
9 input on AmerisourceBergen's program at
10 annual meetings; is that correct?

11 MR. BOGLE: Object to form.

12 THE WITNESS: Counselor,
13 I -- I read it that they were --
14 there was a meeting to talk about
15 suggestions and improvements in
16 AmerisourceBergen's compliance
17 program. That a topic of
18 discussion at those meetings would
19 be any concerns that DEA might
20 have and any other issues of
21 concerns to either of the parties.

22 Beyond that I can't comment
23 on --

24 BY MR. MELTON:

1 Q. You testified that there was
2 a meeting, but this paragraph is in the
3 section titled "Joint Obligations of the
4 Parties," correct?

5 A. It is in the section of
6 the -- of the agreement called "Joint
7 Obligations of the Parties."

8 Q. So there was a joint
9 obligation of the parties to have
10 meetings?

11 A. All I can go is -- by is
12 what the words are on the page. And the
13 words on the page say, "The DEA and
14 AmerisourceBergen shall meet no less than
15 annually at DEA headquarters."

16 Q. Setting aside this document
17 for a moment. Were you present at the
18 2007 DEA industry conference?

19 A. No, I was not.

20 Q. Were you present at the 2009
21 DEA industry conference?

22 A. Again, no, I was not.

23 Q. Let's turn to Page 143 of
24 your report.

1 A. Sure.

2 Q. Okay. Do you see on the
3 first full paragraph towards the end
4 where it says, "ABC effectively ensured
5 that the thresholds rarely would be hit,
6 thus avoiding the need to hold orders"?

7 A. Yes.

8 Q. What is the basis for that
9 statement?

10 A. Well, we can go back through
11 the whole section and talk about how they
12 were setting thresholds and size, if
13 you'd like to go, walk our way through
14 it.

15 But the size of the
16 thresholds were such, and the systems and
17 the way they were implementing the
18 process was such that it was rare that
19 these thresholds would ever be hit and
20 ever be triggered. But we can talk about
21 each of them in detail if you'd like.

22 Q. That's okay.

23 The -- is it your opinion
24 that the program implemented by

1 AmerisourceBergen in 2007 effectively
2 ensured that the thresholds rarely would
3 be hit, thus avoiding the need to hold
4 the orders?

5 A. I'm saying -- can you
6 rephrase the question again for me
7 please?

8 Q. Is it your opinion that the
9 order monitoring program implemented in
10 2007 by AmerisourceBergen effectively
11 ensured that the thresholds rarely would
12 be hit, thus avoiding the need to hold
13 the orders?

14 A. That's what I'm saying.

15 Q. Did the DEA observe that
16 when they conducted their functionality
17 reviews at the five distribution centers
18 in 2007?

19 A. I have no idea what DEA
20 observed or did not observe.

21 Again, if you have something
22 that you'd like me to look at in
23 particular, I'm happy to examine it now.

24 Q. Let's turn to Page 144 of

1 your report.

2 A. Okay.

3 Q. Do you see up at the top,
4 the last sentence of that carryover
5 paragraph where it says, "In the eyes of
6 the DEA's limits, ABC's basic unadjusted
7 thresholds started out at suspicious
8 order levels"?

9 A. I see it.

10 Q. Did the DEA also make that
11 observation when they conducted the
12 functionality reviews at five
13 AmerisourceBergen distribution centers in
14 2007?

15 A. Again, Counselor, I don't
16 know what DEA observed at those five --
17 in those observations. But again, if you
18 have a document you'd like me to review,
19 I'd be happy to review them.

20 Q. I'm just asking for your
21 opinion.

22 A. Without seeing a document, I
23 cannot form an opinion.

24 Q. Let's take a look at

1 Page 145. It's the section that is
2 labeled "C. OMP - Setting the Record
3 Straight."

4 A. Yep, I see it.

5 Q. And it continues to
6 Page 147?

7 A. I see it.

8 Q. Do you recall the documents
9 that you reviewed that were titled
10 "Setting the Record Straight"?

11 A. I do recall them. And I
12 believe they are listed here in the
13 footnotes.

14 Q. If you look at Page 147, the
15 last paragraph of this section, the
16 middle of the paragraph, it says, "I can
17 only conclude that ABC made the change to
18 allow its sales force to provide
19 customers with valuable coaching on how
20 to avoid their orders being labeled as
21 suspicious, thereby undermining the SOM
22 program even further."

23 Do you see that?

24 A. Yep.

1 Q. Now, there's no citation
2 after that statement. So what is the
3 basis for that opinion or conclusion?

4 A. The fact that you had it in
5 the original version and then was
6 stripped out -- the sentence, "Notifying
7 a customer that they had been reported to
8 the DEA or state would defeat the purpose
9 of the monitoring program," was then
10 stripped out of your October version,
11 which is what we're talking about here.

12 So the removal of that
13 sentence, all I -- all I could conclude
14 is you wanted to -- that sentence was
15 removed to allow notifications to occur.

16 Q. In the many documents that
17 you reviewed in this case, you did not
18 find an example of ABC's sales force
19 providing valuable coaching to customers
20 to avoid having their orders labeled as
21 suspicious; is that correct?

22 MR. BOGLE: Object to form.

23 THE WITNESS: I looked at a
24 lot of documents, Counselor. I

1 can't tell you off the top of my
2 head if I saw anything -- a
3 particular document.

4 Again, if there's a
5 particular document that you'd
6 like me to review, I would be
7 happy to do so.

8 BY MR. MELTON:

9 Q. If you had seen such a
10 document, it would be noted in your
11 report; is that correct?

12 A. Counselor, I noted what was
13 relevant to formulate my opinions in the
14 report. You're asking me a hypothetical
15 of a hypothetical document. I can't
16 answer that question.

17 Q. A document that essentially
18 proves your conclusion to be accurate
19 would be relevant to your report,
20 correct?

21 A. If I saw relevant documents,
22 I, again, more than likely would have
23 cited to it. But again, I can't tell you
24 unless you've got a specific document or

1 specific fact pattern, it's hard for me
2 to -- you're asking me to play what if.

3 Q. And there's nothing cited
4 after the statement that we are talking
5 about correct?

6 A. There is no footnote.

7 Q. Okay. Now continuing on
8 Page 147 where it says, "Low volume
9 accounts."

10 A. It does.

11 Q. In the second paragraph,
12 about halfway in, you write, "In other
13 words."

14 Do you see that statement?

15 A. Yes.

16 Q. The statement that begins,
17 "In other words"?

18 A. Mm-hmm. I see the
19 statement.

20 Q. Now, this statement that you
21 make here is essentially paraphrasing
22 something that you found somewhere else,
23 correct?

24 MR. BOGLE: Object to form.

1 THE WITNESS: Could you
2 re-ask the question again?

3 BY MR. MELTON:

4 Q. Sure. It states, "In other
5 words," and then explains what you're
6 trying to get at. So by saying "in other
7 words," it was not in the original
8 document, correct?

9 MR. BOGLE: Object to form.

10 THE WITNESS: It is my
11 reading of the document and what
12 the document actually says
13 referencing back to Footnote 789.

14 BY MR. MELTON:

15 Q. But if Document 789 actually
16 said what you say it says, you would have
17 quoted it, correct?

18 MR. BOGLE: Object to form.

19 THE WITNESS: I might have.
20 I might not have. Counselor,
21 again, you're asking me to play
22 what-if games.

23 BY MR. MELTON:

24 Q. In fact, Footnote 789, you

1 did quote from the document; is that
2 right?

3 A. I did quote from the
4 document.

5 Q. Continuing on in that
6 paragraph, do you see where it says,
7 "Neither Mr. Zimmerman nor Mays in their
8 depositions could provide an alternate
9 rationale for the document"?

10 Do you see that?

11 A. I do.

12 Q. And I notice that there's
13 also no citation listed there; is that
14 correct?

15 A. There is no footnote listed
16 there, no.

17 Q. Had Mr. Zimmerman or
18 Mr. Mays been asked about this in their
19 deposition, would you have cited to the
20 testimony?

21 MR. BOGLE: Object to form.

22 THE WITNESS: Counselor, I
23 don't remember what was in those
24 depositions on this issue. I

1 have -- I'd have to look at the
2 specifics.

3 BY MR. MELTON:

4 Q. Okay. Let's take a look at
5 Page 132 of your report.

6 A. I'm there.

7 Q. The third full paragraph
8 starts with, "This private face also."

9 Do you see that?

10 A. Mm-hmm.

11 Q. So in 2015,
12 AmerisourceBergen engaged FTI Consulting
13 Inc.'s health solutions practice; is that
14 correct?

15 A. That's what this report
16 says, yes.

17 Q. Is there anything wrong with
18 ABC engaging an outside consultant to
19 evaluate their anti-diversion program?

20 A. No. There's nothing wrong
21 with engaging an outside consultant, no.

22 Q. In your 30 years of
23 experience in compliance, this is the
24 type of behavior that we would like to

1 see out of companies; is that correct?

2 A. Well, we have to take it
3 through the whole full circle. We would
4 like to see them engage outside
5 consultants to improve their programs and
6 then actually follow through and make
7 those improvements that are recommended.
8 That would be what we -- that's the real
9 goal of what we're looking for.

10 Q. You reviewed the deposition
11 transcript of David May; is that correct?

12 A. I did.

13 Q. And you take issue with some
14 of the statements that Mr. May made about
15 the FTI findings; is that correct?

16 A. I do.

17 Q. Now, on Page 133 of your
18 report at the top, the last sentence
19 states, "Not only did Mr. May disagree
20 with the findings, but ABC also did not
21 implement any changes in its policies and
22 procedures as a result of the FTI
23 report."

24 Do you see that?

1 A. I do.

2 Q. And it notes that Footnote
3 707 details the basis for that statement,
4 correct?

5 A. That's what it says.

6 Q. Footnote 707 also notes that
7 Mr. May testified that he conducted his
8 own review, "And we made changes to the
9 program."

10 Do you see that?

11 A. Yes.

12 Q. And it says -- in between
13 the two quotes for Footnote 707, it says
14 "but CF"?

15 A. Compare.

16 MR. BOGLE: Wait until he
17 asks you a question.

18 MR. MELTON: That was going
19 to be my question.

20 MR. BOGLE: That's fine. It
21 may have been. I just want to
22 make sure he's actually answering
23 a question.

24 MS. McCLURE: Good guess.

1 BY MR. MELTON:

2 Q. It was a good guess. Do you
3 know who Mr. May was referring to when he
4 said "we made changes to the program"?

5 A. I believe he was referring
6 to ABC, but more precisely than that, no.

7 Q. Are you aware that FTI was
8 hired to evaluate and enhance ABC's order
9 monitoring program in 2014?

10 A. I don't recall seeing any
11 documents on that. I don't.

12 Q. Okay. Would you agree that
13 at least as of 2016, ABC made a number of
14 changes acting on the FTI findings?

15 MR. BOGLE: Object to form.

16 THE WITNESS: Let's go back.

17 Do you have a specific section of
18 the report that you'd like to look
19 at?

20 BY MR. MELTON:

21 Q. Sure. Let's look at Page
22 154.

23 A. Okay.

24 Q. Do you see in the paragraph

1 at the top of the page where it says,
2 halfway through it says, "Therefore,
3 despite Mr. May's contention that FTI's
4 findings were incorrect, it appears that
5 ABC proceeded to act on them in an effort
6 to create 'more standardized, automated
7 and objective processes to drive
8 decisions and processes'?"

9 A. I do see that statement.

10 Q. So it looks like ABC did act
11 on the FTI findings; is that correct?

12 A. Eventually, yes. But again
13 we can go back and look at Mr. May's
14 testimony and that, if I recall the date,
15 we are talking about an event several
16 years prior to that when those findings
17 were -- original findings were presented
18 to ABC.

19 So if you give me a second.

20 Q. I didn't ask you to go back
21 and look at Mr. May's testimony.

22 A. I would like to, I mean,
23 let's be accurate.

24 Q. Do you have Mr. May's

1 testimony?

2 A. No, I know. Let's go back
3 and look at the report, what I say in my
4 report.

5 As I recall the findings,
6 and I can get you the date of when FTI
7 actually made their findings, that
8 several years had transpired. That's --

9 Q. How about Page 132,
10 Footnote 704?

11 A. Yes.

12 Q. What is the date that's
13 listed?

14 A. I have 2015.

15 Q. Is there a month listed?

16 A. August.

17 Q. And a day?

18 A. Yes, there's a day.

19 Q. What is -- what is the date
20 that is listed?

21 A. August 25th.

22 Q. August 25th of 2015,
23 correct?

24 A. Correct.

1 Q. So if we look back at
2 Page 154.

3 A. 2016.

4 Q. So a couple months --

5 MR. BOGLE: Wait for the
6 question.

7 BY MR. MELTON:

8 Q. So a couple months had
9 passed between the FTI findings and the
10 enhancements that were rolled out in
11 2016?

12 MR. BOGLE: Object to form.

13 THE WITNESS: I don't know
14 the exact month that they rolled
15 out in 2016.

16 BY MR. MELTON:

17 Q. Take a look at Page 157.
18 The section continues onto Page 158.

19 A. I see it.

20 Q. Do you recall reviewing
21 audits of ABC's program that were
22 conducted by Michael Mapes?

23 A. I recall the documents that
24 are cited here, yes.

1 Q. And it's your opinion that
2 ABC did not have a robust internal audit
3 process; is that correct?

4 A. That was my opinion, yes.

5 Q. And that's your opinion
6 because Mr. Mapes utilized the checklist;
7 is that correct?

8 MR. BOGLE: Object to form.

9 THE WITNESS: No, that's not
10 my only reason. A checklist, per
11 se, is not the issue. There is no
12 context around it that you'd
13 expect to see in an audit.

14 What were the actual
15 transactions that were reviewed,
16 what was the sample that was
17 pulled, what are the management
18 responses, what's the corrective
19 action plan. All that is part and
20 parcel of a formal audit program.
21 This is more of just a quick and
22 dirty -- as I cite, quality
23 control checklist. It's not a
24 real -- in my opinion, it is not a

1 real formal audit program.

2 BY MR. MELTON:

3 Q. Staying on Page 158. Do you
4 see Section 11.6.1?

5 A. I do.

6 Q. Discussing accountability?

7 A. I do.

8 Q. Now, there are three
9 individuals listed in this section; is
10 that correct?

11 A. There were three of the
12 individuals listed in this section, yes.

13 Q. And we've discussed all
14 three of these individuals today,
15 Mr. Zimmerman, Mr. Mays, and Mr. May; is
16 that correct?

17 A. Yes, they've come up today.

18 Q. Now, you testified yesterday
19 that holding someone accountable could
20 range from a loss of bonus, demotion,
21 transfer, or termination; is that
22 correct?

23 A. Correct.

24 Q. Do you know whether any of

1 these three men have lost the bonus?

2 A. I didn't see anything on the
3 record that showed accountability.

4 Q. Do you know whether any of
5 these three men have been demoted?

6 A. Again, I didn't see -- I
7 didn't see anything in -- in my review of
8 the records.

9 Q. Do you know whether any of
10 these three men have been transferred
11 from their positions?

12 A. Except for the fact
13 Mr. Zimmerman is no longer chief
14 compliance officer, again I didn't see
15 any evidence on the record.

16 Q. Aside from the fact that
17 they've not been fired from
18 AmerisourceBergen, what basis do you have
19 to say that they've not been held
20 accountable?

21 A. I haven't seen anything that
22 shows they have been accountable or shows
23 they have been accountable.

24 Again, Counselor, if there's

1 something you'd like me to consider and
2 look at I'll be happy to look at right
3 now.

4 Q. As you sit here today, do
5 you intend to supplement your report with
6 regard to AmerisourceBergen?

7 A. Again, I reserve the right
8 to supplement my report based on new
9 information as it becomes available, and
10 that's pertinent and germane to what I
11 opined on. But I have no present plan at
12 the moment for amending the report.

13 Q. Are you relying today on any
14 notes that you made to refresh your
15 recollection regarding AmerisourceBergen
16 in advance of testifying today?

17 A. No. I'm testifying from
18 my -- we went through my report.

19 Q. Did you bring any notes with
20 you today regarding AmerisourceBergen?

21 A. I don't have any notes with
22 me right now.

23 Q. Just one more item that I
24 want to clear up. We talked about this a

1 little bit at the beginning, but the --
2 we've reviewed the transcript from
3 yesterday and the -- the -- when I
4 thought I heard ABC, I'll represent to
5 you that the transcript says, "I was
6 brought in with ABC, I think at some
7 point, to advise on antikickback and
8 FCA."

9 You're now saying today that
10 your testimony did not refer to
11 AmerisourceBergen, correct?

12 A. I'm saying today if I said
13 that I said I didn't recall. I was quite
14 accurate in saying I didn't recall what
15 I'd said yesterday. Thank you for going
16 back.

17 Again, I don't have any
18 specific recollection of a specific
19 project, no, Counselor, I don't.

20 I thought I did. I was
21 probably mistaken.

22 Q. So you have no specific
23 recollection of doing any work for ABC?

24 A. I did not -- no specific

1 recollection of doing work for ABC, no.

2 I think what I would have been referring
3 to, if I did anything, would have been a
4 partner in the Deloitte practice would
5 have consulted me and I would have made
6 some statements about antikickback and --
7 and FCA.

8 But again, you're asking me
9 from awhile ago, I don't rightly recall.

10 Q. Statements about
11 antikickback, this -- what you just
12 mentioned --

13 A. You had asked me --

14 MR. BOGLE: Wait, wait,
15 wait.

16 BY MR. MELTON:

17 Q. What you just mentioned
18 about the -- the partner at Deloitte,
19 statements about antikickback and FCA, to
20 AmerisourceBergen?

21 A. Again, I don't rightly
22 recall. I was a compliance consultant in
23 the form that I am in now within Deloitte
24 as well. So I -- people would come to me

1 and say well, what do you think about,
2 what are the rules on, that's what I'm --
3 that's what I have a vague recollection
4 of.

5 Q. Did you or did you not do
6 any work --

7 A. I did not do --

8 MR. BOGLE: Whoa, whoa,
9 whoa. Let him finish.

10 THE WITNESS: I'm sorry.

11 BY MR. MELTON:

12 Q. Did you or did you not do
13 any work at Deloitte regarding
14 AmerisourceBergen?

15 A. To the best of my knowledge,
16 counselor, I did not bill any time to
17 AmerisourceBergen as a client while I was
18 at Deloitte.

19 Q. I didn't ask you whether you
20 billed any time. My question was whether
21 you did any work regarding
22 AmerisourceBergen.

23 A. That's the best way I can
24 tell you whether or not I did work, would

1 be -- if I did work, it would have been
2 billed time. And I don't recall billing
3 any time to AmerisourceBergen as an
4 account.

5 Q. So if you did not bill time
6 to AmerisourceBergen, then you did not do
7 work for AmerisourceBergen, correct?

8 A. As far as I -- it certainly
9 would have been unbillable time. Like I
10 said, I don't rightly recall. I'm sorry.
11 It's been a while.

12 Q. So you don't know whether
13 you did any work for AmerisourceBergen?

14 MR. BOGLE: Object to form.
15 Asked and answered.

16 THE WITNESS: I will answer
17 the question the best I can again,
18 Counselor. I did not bill any
19 time to the AmerisourceBergen
20 account that I recollect doing
21 when I was at Deloitte.

22 MR. MELTON: At this time
23 I'm going to pass the witness.
24 Let's go off the record.

1 THE VIDEOGRAPHER: Going off
2 the record. 11:31 a.m.

3 (Short break.)

4 THE VIDEOGRAPHER: We are
5 back on the record at 11:46 a.m.

6 - - -

7 EXAMINATION

8 - - -

9 BY MR. HYNES:

10 Q. Good morning, Dr. Whitelaw.
11 My name is Paul Hynes. We met off the
12 record. I represent CVS in this case.

13 First, sir, do you have any
14 opinions about CVS that are not in your
15 report or your supplemental report?

16 A. No, sir. My report is, and
17 supplemental are part of the record.

18 Q. Okay. And do you have any
19 intention currently to offer any opinions
20 about CVS that are not in either report?

21 A. I have no current intentions
22 to do that.

23 Q. Okay. And do your reports
24 cite all the evidence that you're relying

1 on to support your opinions about CVS?

2 A. With the exception of my
3 30 years' experience of being a
4 compliance officer and -- but if you're
5 looking for documents, yes.

6 Q. Okay. And do you have any
7 intention currently to rely on any
8 evidence not cited in your reports to
9 support your opinions about CVS?

10 A. Again, other than my
11 30 years' experience and my conversations
12 that we talked about in depth with
13 Mr. Rafalski, no. But those are cited --
14 that conversation is cited in the report
15 too, so...

16 Q. I want to talk about your
17 review of CVS documents. Did you follow
18 the same process for CVS that you
19 described yesterday that you requested
20 certain categories of documents from
21 plaintiffs' counsel?

22 A. Yes, sir, I did.

23 Q. I want to turn to pages 276
24 and 77 of your report. It's in the

1 appendices.

2 A. Okay.

3 Q. You list there 16 CVS
4 depositions. Did you review all of those
5 deposition transcripts or just portions?

6 A. I can't tell you at this
7 point whether I reviewed all or portions
8 at this point, considering the number of
9 deposition transcripts that I worked
10 with.

11 Q. Can you tell me whether you
12 reviewed the entirety of any of those
13 depositions?

14 A. I believe I reviewed the
15 entirety of some of them, but I can't
16 tell you which ones right off the top of
17 my head right now.

18 Q. Okay. Did you request any
19 depositions from counsel that were not
20 provided to you?

21 A. I -- everything I requested
22 from counsel was provided for me if they
23 could find it in their files.

24 Q. Okay. And did you watch any

1 videos of the CVS depositions listed in
2 your appendices?

3 A. No, I reviewed the written
4 transcripts.

5 Q. Sir, did you prepare any
6 notes to possibly be used to refresh your
7 recollection during this deposition
8 related to CVS?

9 A. Yes, I did.

10 Q. Okay. I would just ask that
11 if you do use those notes, you tell me.
12 Is that fair?

13 A. That -- ask the gentleman to
14 my left.

15 MR. BOGLE: Yes. If he uses
16 them, yeah, of course, yes.

17 BY MR. HYNES:

18 Q. I want to talk about how you
19 drafted your report. Did plaintiffs'
20 counsel draft any of the CVS sections of
21 your reports?

22 A. No, they did not.

23 Q. Did they draft any of the
24 CVS paragraphs of your reports?

1 A. No, they did not.

2 Q. Any sentence in the CVS
3 sections of your reports?

4 A. No. I drafted everything.

5 Q. Did they provide any edits
6 to the CVS sections of your reports?

7 A. No they didn't provide
8 edits. They may have provided comments
9 where I was factually incorrect or had a
10 wrong Bates stamp number or something
11 along those lines, but no.

12 Q. Were those comments conveyed
13 to you orally or in written form?

14 A. Probably both.

15 Q. Okay. So is it your
16 testimony, sir, that not a single word in
17 the CVS sections of your report came from
18 plaintiffs' counsel?

19 A. It's my testimony I wrote
20 this report soup to nuts, yes.

21 Q. Did plaintiffs' counsel
22 provide you with a list or outline of
23 opinions to give about CVS?

24 A. Absolutely not.

1 Q. A list or outline of CVS
2 issues to consider?

3 A. No. That I recall, no.

4 Q. A list or outline of CVS
5 facts to address?

6 A. Again, not that I recall.

7 Q. Sir, I want you to turn to
8 Page 161 of your report, please.

9 A. I'm here.

10 Q. Okay. And it's the last
11 sentence above Section 12.3. And it's
12 actually the second-to-last line going
13 onto the last line there. You state, "If
14 the mode model had a remedial level, I
15 would place a CVS program there."

16 Do you see that?

17 A. I do.

18 Q. When you say the CVS
19 program, are you referring to the CVS SOM
20 program?

21 A. I'm referring to the CVS
22 anti-diversion program, of which SOM is a
23 key component of it.

24 Q. Okay. Have you evaluated

1 any other CVS anti-diversion programs?

2 MR. BOGLE: Object to form.

3 THE WITNESS: I'm not sure I
4 understand.

5 BY MR. HYNES:

6 Q. Have you evaluated any CVS
7 anti-diversion programs other than the
8 CVS SOM program?

9 MR. BOGLE: Object to form.

10 THE WITNESS: Again, I think
11 I have covered this before. The
12 focus was on SOM. They all fit
13 together. I focused on -- I did
14 focus on suspicious order
15 monitoring. In the context of a
16 broader anti-diversion program, in
17 the context of a broader corporate
18 compliance program.

19 BY MR. HYNES:

20 Q. Okay. So you didn't review
21 any documents related to CVS's theft and
22 loss reporting?

23 A. No, I did not.

24 Q. Or any documents related to

1 its pharmacy-level anti-diversion
2 programs?

3 A. No, I did not.

4 Q. Okay. The model that you
5 discuss here, have you ever, in all the
6 times that you've used that model, found
7 an SOM program to score above the
8 foundational level?

9 MR. BOGLE: For clarity, are
10 you talking about Figure 2? When
11 you say model? I just want to
12 make sure --

13 MR. HYNES: Yeah.

14 THE WITNESS: I don't know
15 what model you're talking about.

16 BY MR. HYNES:

17 Q. The -- yeah, Figure 2.
18 Where -- the one in front of you there.
19 This model right here.

20 A. That model?

21 Q. Yeah.

22 A. And all the time that I've
23 used it for an SOM?

24 Q. Yeah.

1 A. Applied to an SOM program
2 alone?

3 Q. Yes, have you ever found,
4 when you applied it to a SOM program,
5 have you found such a program to score
6 above the foundational level?

7 A. No, I have not.

8 Q. Before you were engaged in
9 this case, had you ever used this model
10 to evaluate an SOM program?

11 A. No, I had not. But it is a
12 standard compliance maturity model that
13 I've used to evaluate compliance
14 programs.

15 Q. But not an SOM program
16 before you were --

17 A. Not an SOM --

18 Q. -- engaged in this case?

19 A. -- program, per se.

20 Q. I want to turn to --

21 MR. BOGLE: Just wait until
22 he finishes.

23 BY MR. HYNES:

24 Q. -- CVS's distribution

1 business. You know that CVS is a
2 national chain pharmacy, correct?

3 A. Yes, sir, I do.

4 Q. Okay. And I think you state
5 in your report, it has 9,800 retail
6 pharmacies. Page 159.

7 A. I believe that's --

8 Q. Approximately.

9 A. Approximately. That number
10 rings a bell.

11 Q. I'm not trying to test you
12 on that.

13 Are -- are you aware how
14 many retail pharmacies CVS has in
15 Cuyahoga and Summit Counties?

16 A. Not off the top -- the
17 number? I don't have a hard number off
18 the top of my head.

19 Q. Is that something you looked
20 into when you were evaluating CVS's SOM
21 program?

22 A. Again, I evaluated a lot of
23 different things in the SOM program. And
24 I may have looked into it. Again, I

1 can't rightly recall. It doesn't -- I
2 don't have a recollection of it for you.

3 Q. Okay. And are you aware of
4 how many CVS warehouses distributed to
5 CVS retail pharmacies in Cuyahoga and
6 Summit County?

7 A. My understanding, based on
8 my review, was it was in the -- the
9 Indianapolis distribution center was
10 distributing into Summit and Cuyahoga
11 County. That's what I have.

12 Q. Okay. And are you aware
13 that like Walgreens, CVS only distributes
14 to itself, to -- to its own pharmacies?

15 A. Yeah, I believe that was
16 what was noted in my report.

17 Q. So it doesn't distribute to
18 pain clinics, correct?

19 A. I know it distributes to its
20 own pharmacies.

21 Q. Okay. So you -- you are
22 aware then that it doesn't distribute to
23 pain clinics?

24 A. If they are not owned by

1 CVS, I'm aware that they only distribute
2 to CVS entities.

3 Q. Okay. Are you familiar with
4 the pharmaceutical drugs distributed by
5 CVS warehouses?

6 MR. BOGLE: Object to form.
7 Vague and overbroad.

8 THE WITNESS: Can you be
9 more specific?

10 BY MR. HYNES:

11 Q. Are you aware that CVS does
12 not distribute Schedule II controlled
13 drugs?

14 A. Does not.

15 Q. Yes.

16 A. Yes, I am aware of that.

17 Q. And are you aware that of
18 the prescription opioids at issue in this
19 case, CVS only distributed hydrocodone
20 combination products?

21 A. Yes, I am aware of that.

22 Q. All right. I'm going to
23 refer to those as HCPs throughout the
24 day. It's just easier to say.

1 A. Okay.

2 Q. So CVS produced
3 transactional data in this case showing
4 all of its shipments of controlled and
5 noncontrolled drugs to Cuyahoga and
6 Summit County. Have you reviewed that
7 transactional data?

8 A. No, I have not reviewed all
9 of that transactional data.

10 Q. Have you reviewed any of it?

11 A. Again, I don't recall.

12 Q. Okay. So is it fair to say
13 you're not familiar with the percentage
14 of shipments CVS made to Cuyahoga and
15 Summit County that were controlled drugs
16 versus noncontrolled drugs?

17 A. I would say that if it's
18 not -- not referenced in the report, I
19 don't recall it.

20 Q. And you are also not aware
21 of the percentage of shipments that CVS
22 made to those two counties that were HCPs
23 versus other kinds of drugs?

24 A. Again, if it's not in the

1 report I don't recall it.

2 Q. Okay. Did you make a
3 determination whether any of the
4 shipments in the transactional data that
5 CVS made to those two counties were
6 diverted?

7 MR. BOGLE: Object to form.

8 THE WITNESS: I'll go back
9 to where -- what I was asked to
10 look at.

11 BY MR. HYNES:

12 Q. Okay.

13 A. I was asked to look at the
14 SOM program, anti-diversion program,
15 corporate compliance program, from a
16 process, procedure, and following it
17 standpoint.

18 That was what I was asked to
19 do, and that's what this report covers.

20 Q. Okay. That's -- that's
21 fair. I just want to make sure then, you
22 didn't -- you didn't take it a step
23 further and determine whether any HCPs
24 distributed by CVS in the Cuyahoga and

1 Summit Counties were diverted?

2 A. I stayed and looked at it
3 from a corporate compliance program,
4 effectiveness setup, and whether it was
5 followed, and that's as far as my report
6 goes.

7 Q. Okay. Could you answer -- I
8 don't want to be difficult. I would like
9 a yes or no answer. It's a pretty simple
10 question.

11 Did you determine whether
12 any of those shipments were diverted?

13 A. No, sir. I did not --

14 Q. Thank you.

15 A. -- determine that.

16 Q. Sir, you discuss -- let's
17 get to the page. Let's turn to Pages 161
18 and 162 of your report.

19 A. Okay.

20 Q. You discuss there two CVS
21 pharmacies in Indiana. One in Vincennes,
22 Indiana, and one in Columbus, Indiana.

23 A. Mm-hmm.

24 MR. BOGLE: Make sure you

1 say yes or no.

2 THE WITNESS: Yes, I do.

3 BY MR. HYNES:

4 Q. Sir, you cite the volume of
5 HCP tablets distributed to those stores
6 between January 2012 and October 2013,
7 correct?

8 A. I do.

9 Q. And that's based on an
10 e-mail that a DEA agent sent to a CVS
11 employee, correct?

12 A. Correct.

13 Q. Did you go back and --
14 strike that.

15 Did you consider any other
16 data about these stores such as the
17 overall volume of controlled substances
18 that they dispensed?

19 A. What I considered, or at
20 least asked for, was additional evidence
21 of due diligence by CVS on these
22 particular stores in response to this
23 query about dosages. And I didn't really
24 see an effective due diligence file.

1 Q. So you didn't -- you didn't
2 see any due diligence files related to
3 these two pharmacies?

4 A. I did not.

5 Q. Okay. And you are aware,
6 and I just said it. But you are aware
7 these pharmacies are located in Indiana,
8 right?

9 A. I am aware that these two
10 pharmacies are located in Indiana. But
11 again CVS, like all the other defendants
12 in this case, were running national --

13 Q. That's fair. That --

14 A. -- programs.

15 Q. But I just want to get to
16 your point about due diligence files.
17 And this case involves Cuyahoga and
18 Summit Counties. Okay?

19 A. I'm aware of that.

20 Q. Are you aware that the
21 discovery links in this case only
22 obligated CVS to produce due diligence
23 files related to Cuyahoga and Summit
24 Counties?

1 A. I'm not sure I knew exactly
2 what the complete limits of your
3 discovery requests were. Again, I
4 requested due diligence files on these --
5 on these stores and I didn't see
6 anything.

7 Q. So you are not aware that
8 CVS did not have an obligation to produce
9 due diligence files related to
10 distribution to these stores?

11 A. Not that I can rightly
12 recall.

13 Q. That's not something
14 plaintiffs' counsel told you?

15 A. Again, I don't recall.

16 Q. Okay. That's fine.

17 Sir, are you aware of any
18 HCPs dispensed by these two stores that
19 ended up in Cuyahoga and Summit Counties?

20 A. No, I didn't. Again, it was
21 outside the scope of this report.

22 Q. Okay. On Page 162 you
23 discuss three corporate integrity
24 agreements that CVS entered into with the

1 Office of Inspector General for HHS.

2 A. I do.

3 Q. And you'd agree, sir, that
4 those agreements are not related to CVS's
5 SOM system?

6 A. Yes. As -- as stated in the
7 report.

8 Q. Yeah. You state in your
9 report that they are not even related to
10 controlled substances, correct?

11 A. That is correct.

12 Q. And on 162 going over to
13 163, you discuss three settlement
14 agreements that CVS entered into with
15 DEA; is that right?

16 A. That is correct.

17 Q. And the first one relates to
18 sales of PSE, pseudoephedrine products.

19 A. It does.

20 Q. In California and Nevada in
21 2007 and 2008, correct?

22 A. Correct.

23 MR. BOGLE: Just make sure
24 he's totally done. Give him maybe

1 a second to make sure he's totally
2 done.

3 MR. HYNES: That's fine.
4 That's fine.

5 BY MR. HYNES:

6 Q. So those agreements did not
7 involve controlled substances, did they,
8 that agreement?

9 A. They -- that agreement did
10 not.

11 Q. And it did not involve
12 Cuyahoga and Summit Counties?

13 A. No, sir, it did not.

14 Q. And then you talk about two
15 other agreements. One relates to
16 recordkeeping violations by CVS retail
17 pharmacies in Oklahoma, correct?

18 A. I do.

19 Q. And the other -- but is that
20 what one of them relates to?

21 A. I do talk about an Oklahoma
22 case, yes.

23 Q. Okay. And that involves a
24 recordkeeping violations by CVS retail

1 pharmacies in Oklahoma?

2 A. To the best of my
3 recollection, yes.

4 Q. Okay. Thanks. And the
5 other one relates to the theft and loss
6 reporting by CVS retail pharmacies in two
7 counties in New York; is that correct?

8 A. That is correct.

9 Q. Okay. So neither of those
10 settlements involved CVS's SOM program,
11 did they?

12 A. No.

13 MR. BOGLE: Object to form.

14 BY MR. HYNES:

15 Q. And neither involved CVS
16 warehouses in Indianapolis, Indiana --

17 A. To the best --

18 Q. -- or Chemung, New York?

19 A. To the best of my knowledge,
20 no.

21 Q. And neither involved CVS
22 retail pharmacies in Cuyahoga and Summit
23 Counties?

24 A. Again to the best of my

1 knowledge, no, they did not.

2 Q. Okay. Sir, are you aware
3 that CVS has never entered into a
4 settlement agreement with DEA related to
5 its SOM program for controlled
6 substances?

7 A. I am aware.

8 Q. Okay. And you're aware that
9 CVS has never paid a fine to DEA related
10 is its SOM program for controlled
11 substances?

12 A. Yes.

13 Q. And you're aware that CVS
14 has never been involved in any litigation
15 with DEA related to its SOM program for
16 controlled substances?

17 A. At least what litigation
18 that I know about that's on the public
19 record, yes, I would agree with your
20 statement.

21 Q. Did you -- okay. And did
22 you go look at the public record to
23 investigate --

24 A. I did.

1 Q. -- CVS litigation?

2 MR. BOGLE: Wait until he's
3 done.

4 BY MR. HYNES:

5 Q. You answered. That's okay.

6 A. I did.

7 MR. BOGLE: You're going to
8 get strangled by the court
9 reporter here in a minute.

10 THE WITNESS: I know she's
11 going to kill me.

12 BY MR. HYNES:

13 Q. Apologize to her, not to me.

14 THE WITNESS: Sorry,
15 Michelle.

16 BY MR. HYNES:

17 Q. All right. Let's talk about
18 the automated SOM system that you
19 discussed in your -- in the CVS section
20 of your report.

21 Are you aware that that
22 system was designed by a company called
23 Cegedim Dendrite?

24 A. Can we go to the section of

1 the report --

2 Q. Yeah.

3 A. -- that you're referring to?

4 Q. Sure.

5 A. Where are you referring to,
6 would be helpful to know.

7 Q. You discuss throughout most
8 of the --

9 A. I guess, is there a
10 particular section you'd like to --

11 Q. No, I don't have one in mind
12 right now. I'm just --

13 A. Okay. That's all right.

14 Q. I have some very general
15 questions about the system. Are you
16 aware that it was designed by a company
17 called Cegedim Dendrite?

18 A. Yes, sir, I am.

19 Q. Are you familiar with that
20 company?

21 A. Yes, I am familiar with the
22 company.

23 Q. Are you aware that it
24 designed SOM systems for several

1 different -- actually many different DEA
2 registrants?

3 A. I'm -- I'm aware they had a
4 DEA SOM program -- practice. I would
5 assume that they designed multiple
6 systems for multiple clients, but it's an
7 assumption.

8 Q. Okay. And are you also
9 aware that the company was -- or at least
10 its DEA compliance division was run by
11 Ronald Buzzeo?

12 A. I'm familiar with the name,
13 yes.

14 Q. You are. Have you ever met
15 Mr. Buzzeo?

16 A. This entire -- Counselor,
17 you're seeing a puzzled look because I've
18 gone to lots of conferences over 30
19 years. It's entirely possible our paths
20 have crossed. I don't rightly recall the
21 man, but --

22 Q. Okay.

23 A. -- it's entirely possible
24 that we shook hands at some point at some

1 conference.

2 Q. Okay. Conferences. Sir,
3 the DEA held distributor conferences in
4 2013, '15, and '16. Did you attend any
5 of those?

6 A. No, I did not.

7 Q. Okay. And they also -- the
8 DEA also held national conferences on
9 pharmaceutical and chemical diversion
10 every year from 2008 to '12 and then 2014
11 and '17. Did you attend any of those?

12 A. No, I did not.

13 Q. Okay. And then it also
14 held -- it's held several practitioner
15 awareness conferences since 2018. Have
16 you attended any of those?

17 A. No.

18 Q. Okay. And going back to
19 Mr. Buzzeo. Are you aware that he
20 previously worked at the DEA?

21 A. Yes, I am aware of that.

22 Q. Do you know what his
23 position was?

24 A. No, sir, I don't recall.

1 Q. Okay. If I told you that he
2 was the former deputy director of the
3 DEA's office of diversion control, do you
4 have any reason to think that's not
5 accurate?

6 A. I don't have any reason to
7 dispute it one way or another. I have no
8 opinion.

9 Q. Okay. All right. Thank
10 you.

11 We're going to talk about
12 this. So I'm just going to call it the
13 Buzzeo system. It's a lot easier to say
14 than Cegedim Dendrite. Is that all -- is
15 that fair? That's what we've called it
16 in our depositions?

17 A. That's fair.

18 Q. Okay. Are you familiar with
19 the algorithm used by the Buzzeo system?

20 A. Yes, I'm familiar with the
21 documents that I reviewed that discuss
22 the algorithm from the Buzzeo system.

23 Q. Are you familiar with how
24 the algorithm works?

1 A. In general terms, yeah. I'm
2 not a statistician.

3 Q. Okay. So could you explain
4 to me the coefficients and the math
5 behind it?

6 A. Absolutely not.

7 Q. Okay. Did you try to learn
8 the math behind it?

9 A. No. I'm not a statistician.

10 Q. Okay. Then, is it fair to
11 say that you're not giving an opinion
12 about the sufficiency of the algorithm
13 itself, just focused on the algorithm?

14 A. I am not giving an opinion
15 on the sufficiency of the algorithm
16 itself. What I was talking about was how
17 the algorithm ended up being used and was
18 put into practice and process.

19 Q. Yeah. And we'll talk about
20 that. Okay. And are you familiar with
21 the daily report that was generated by
22 the algorithm?

23 A. Well, I guess we have to be
24 specific about what period of time. Are

1 you referring to the IRR?

2 Q. Yes, the IRR?

3 A. Which -- which report --

4 Q. Yeah, the IRR.

5 A. Yes, I am familiar with the
6 IRR report.

7 Q. Thank you. And did you
8 review any IRRs?

9 A. I reviewed IRRs, yes.

10 Q. How many?

11 A. I don't remember.

12 Q. How did you select the ones
13 you reviewed?

14 A. I asked for IRRs. Please
15 submit -- you know, give me IRR reports
16 to review. I didn't --

17 Q. And counsel provided those
18 to you?

19 A. Counsel provided me with
20 what they had.

21 Q. You don't know how many?

22 A. I don't recall.

23 Q. Okay. Do you know if you
24 reviewed -- these were used from

1 roughly -- I think the ones that we were
2 able to locate and produce from 2010
3 through early 2014. Did you review IRRs
4 from, you know, each year or --

5 A. Counsel --

6 Q. -- a representative sample?

7 MR. BOGLE: Wait until he's
8 done.

9 THE WITNESS: I reviewed the
10 sample. I can't tell you how I
11 picked the sample. And I can't
12 tell you what I remember from the
13 sample at this point in time. I
14 reviewed a lot of documents.

15 BY MR. HYNES:

16 Q. Okay. Page 167 of your
17 report talks about --

18 A. Which page, please?

19 Q. 167.

20 A. I'm sorry.

21 Q. No, no. I talk fast. You
22 talk about an IRR for the Indianapolis
23 distribution center from November 30,
24 2010.

1 Do you see that?

2 A. I do.

3 Q. Do you recall reviewing that
4 IRR?

5 A. I do actually.

6 Q. Okay. And is it possible
7 that that was the only IRR you reviewed?

8 A. I could go back to my
9 reliance materials and try to drag --
10 drag it out for you. I don't remember.

11 Q. Okay. Okay. Then I'll move
12 on. Thank you.

13 Can you tell me what the
14 average size of an IRR is? Like, how
15 many -- how many pages are typically in
16 an IRR?

17 A. Again, I can tell you what I
18 reviewed and the pages that I got from
19 that. Again, I can't tell you what an
20 average number of pages. I didn't do an
21 average page count.

22 Q. Okay. Did you look to see
23 on average how many HCP orders were in an
24 IRR?

1 A. Again, I can remember
2 reviewing the IRR. I can't be more
3 specific at this point in time.

4 Q. Okay. Are you familiar with
5 the data that's presented for an order on
6 the IRR?

7 A. Again, I've looked at an
8 IRR. Can I recall the exact fields that
9 are on there? No. But if you have a
10 document you'd like to show me,
11 counselor, I'm happy to look at it again.

12 Q. So you can't tell me what
13 the binary day related to, the binary day
14 field related to?

15 A. As I said, I don't remember
16 the specifics fields on the IRR. Again,
17 if there's a document you'd like me to
18 look to, I'll be happy to look to it.

19 Q. I don't have one with me
20 here, sir. So I'm sorry. I just want
21 to -- did you make any effort to
22 understand the various different data
23 fields presented on the IRR?

24 A. Counselor, I looked at the

1 IRR. I examined the IRR. I made an
2 effort to look at the fields. Beyond
3 that I can't tell you. I -- you are
4 asking for precision I can't give you.
5 But again, I'm happy to look at a
6 document if you have one.

7 Q. Okay. Sitting here today,
8 you can't tell me what for example, the
9 PZ scores are, or the -- the trend above
10 month or the trend slip. You can't tell
11 me what those data fields --

12 A. No, I cannot tell you.

13 Q. Okay. Sir, I'll move to
14 Page 173 of your report.

15 A. Which page, please?

16 Q. 173.

17 A. Okay.

18 Q. And I want to draw your
19 attention -- I'll let you get there
20 first. It's the first full paragraph on
21 that page.

22 A. Okay.

23 Q. And it's the -- the second
24 to last sentence in that paragraph. You

1 write, "If an order is more likely to fit
2 the DEA's definition of a suspicious
3 order, the CCS-SOMS program, 'pends' or
4 flags an order that may be suspicious."

5 Do you see that?

6 A. I do see that.

7 Q. Okay. And then moving down
8 under Section 3, "Item Review Reports."
9 I want to draw your attention to the
10 first sentence, and -- and after the
11 comma you write, "The IRR became the
12 vehicle by which pending orders (i.e.,
13 orders that scored above .15 and thus
14 were suspicious)."

15 So I just -- if you can help
16 me.

17 Is it -- is it your
18 recollection or your view that an order
19 flagged on the IRR was an order that may
20 be suspicious and needed to be
21 investigated, or -- or it was an order
22 that was suspicious?

23 A. What I'm saying is that if
24 the order flagged from the algorithm is

1 suspicious in the sense it needs further
2 investigation.

3 Q. You're not saying that every
4 order that flags on the IRR has to be
5 reported to DEA?

6 MR. BOGLE: Object to form.

7 THE WITNESS: Can you be
8 more precise?

9 BY MR. HYNES:

10 Q. Yes.

11 You're -- you're familiar
12 with the requirement that a DEA
13 registrant report a suspicious order to
14 DEA?

15 A. Yes.

16 Q. Correct?

17 A. I am familiar with it.

18 Q. Okay. So is it your opinion
19 that CVS was obligated to report to DEA
20 every order that flagged on an IRR?

21 A. I believe my opinion has
22 been consistent throughout, which is any
23 order that flagged on an IRR needed
24 further investigation to determine

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30. [REDACTED]

1 BY MR. HYNES:

2 Q. But sitting here today you
3 don't recall any testimony that went to
4 that issue?

5 A. I don't recall anything that
6 stands out that I can remember.

[illegible]

[illegible]

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[REDACTED]

2

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4

Q. But you didn't -- you didn't

5

examine this issue at the transactional

6

level, yes or no?

7

MR. BOGLE: Object to form.

8

THE WITNESS: Again, that

9

wasn't the purpose of the review.

10

BY MR. HYNES:

11

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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█ MR. HYNES:

24

Q. Sir, the IRR was first

1 reviewed at the Lumberton distribution
2 center, right?

3 A. That's my recollection.

4 Q. By Mr. Mortelitti?

5 A. That is also my
6 recollection.

7 Q. And you write he had no
8 prior experience with suspicious order
9 monitoring.

10 A. I can go back and look at
11 the report, but yes, I recall that.

12 Q. Okay. But you also don't
13 have any prior experience with suspicious
14 order monitoring, do you?

15 MR. BOGLE: Object to form.
16 Misstates testimony.

17 THE WITNESS: I'm not sure I
18 understand what you mean. I do
19 have experience working in
20 regulated -- I did -- I have
21 reviewed the requirements around
22 being a suspicious order
23 monitoring. If you asked if I
24 built and designed a system, no, I

1 haven't. But that's already on
2 the record.

3 BY MR. HYNES:

4 Q. You've never operated an SOM
5 system either, have you?

6 MR. BOGLE: Object to form.

7 THE WITNESS: No. My role
8 is -- no, I have not.

9 BY MR. HYNES:

10 Q. You've never audited an SOM
11 system, have you?

12 MR. BOGLE: Object to form.

13 THE WITNESS: No, I have not
14 audited an SOM system. But I
15 have -- I have audited PDMA
16 systems which are substantially
17 similar.

18 BY MR. HYNES:

19 Q. But not an SOM system?

20 A. Not an SOM system.

21 Q. And you write that "CVS had
22 one person doing the daily review of the
23 IRR."

24 But there were people in the

1 field who investigated orders that were
2 referred by Mr. Mortelitti, weren't
3 there?

4 A. Again, I didn't see evidence
5 of those orders being investigated in the
6 field.

7 Q. You didn't see evidence of
8 those orders being investigated in the
9 field?

10 A. I did not see the people
11 that he's referring to in his testimony,
12 the field analyst.

13 Q. Are you aware that -- that
14 the plaintiffs did not take the
15 deposition of any of those people?

16 MR. BOGLE: Object to form.
17 BY MR. HYNES:

18 Q. Are you aware that -- that
19 the plaintiffs chose not to take the
20 deposition of any of those people?

21 MR. BOGLE: Object to form.

22 THE WITNESS: No, I'm not.

23

1

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6

Q. But you don't believe him?

7

MR. BOGLE: Object to form.

8

THE WITNESS: It's not a

9

question of belief. It's a

10

question of I did not see any

11

documentation to support the claim

12

that he was making.

13

It's not a question of

14

belief. It's just I didn't see

15

anything on the record one way or

16

the other.

17

BY MR. HYNES:

18

Q. Do you find Mr. Mortelitti

19

to be credible?

20

MR. BOGLE: Object to form.

21

THE WITNESS: I'm not making

22

a judgment on Mr. Mortelitti's

23

credibility or -- one way or the

24

other. I'm simply looking at what

1 he's saying and saying can I find
2 evidence one way or the other to
3 support it.

4 In a typical way that you do
5 an audit. The -- the audit says
6 we're doing some -- we're doing X
7 and you go to look for support
8 behind that to see whether X is
9 actually happening or not.

10 What I'm saying is I saw an
11 absence on the record.

12 BY MR. HYNES:

13 [REDACTED]

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MR. HYNES: I move to

strike -- to strike everything

after "again I don't recall" --

"recall it."

BY MR. HYNES:

Q. Turning to Page 179. You

say, "Ultimately Ms. Hinkle gained two

1 loss prevention analysts assigned to the
2 SOM program."

3 Who are -- who are the two
4 loss prevention analysts you're referring
5 to?

6 A. I'd have to go back and
7 look -- and look at her testimony and go
8 back to -- refer to the report and read
9 it. Do you want to take the time?

10 Q. The names aren't in your
11 report.

12 A. Then I'd have to go back and
13 reconstruct it. I don't rightly know the
14 names off the top of my head.

15 Q. Okay. And are you aware
16 that at some point in mid 2012, the IRR
17 process shifted to the Indianapolis DC?

18 A. I am -- I do have
19 recollection of that.

20 Q. You do?

21 A. I do.

22 Q. Okay. And can you tell me,
23 when the program was in Indianapolis, who
24 worked on it?

1 A. I don't recall at this
2 point.

3 Q. You don't recall. Are you
4 aware of any -- did you see any evidence
5 indicating that when the program was in
6 Knox -- excuse me, was in Indianapolis,
7 that any outside -- outside consultants
8 who were former DEA agents assisted with
9 the process?

10 A. Is there a specific document
11 or a specific section you're referring
12 to, counsel? Because at this point I'm
13 not sure what you're asking.

14 Q. I'm just asking sitting here
15 today, do you recall reviewing any
16 evidence, any documents, or any testimony
17 indicating that outside consultants who
18 were former DEA agents assisted with the
19 operation of the SOM program when it was
20 in Indianapolis.

21 MR. BOGLE: Object to form.

22 BY MR. HYNES:

23 Q. It's a yes or no question.

24 A. I don't have any

1 recollection of any -- of seeing those
2 documents, but again, if there's
3 something you would like me to review,
4 I'd be happy to review it.

5 MR. BOGLE: When you reach a
6 good stopping point, I was going
7 to break for lunch.

8 MR. HYNES: Let's go off the
9 record for a moment.

10 THE VIDEOGRAPHER: Going off
11 the record, 12:45 p.m.

12 - - -

13 (Lunch break.)

14 - - -

15 A F T E R N O O N S E S S I O N

16 - - -

17 THE VIDEOGRAPHER: We are
18 back on the record at 1:34 p.m.

19 - - -

20 EXAMINATION (Cont'd.)

21 - - -

22 BY MR. HYNES:

23 Q. Welcome back, Dr. Whitelaw.

24 A. Thank you, sir.

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Q. You are aware, aren't you,
that CVS produced some of its DEA SOPs to
the DEA during DEA inspections? Have you
seen documents indicating that?

A. Again, I looked at a lot of
documents, Paul. I don't -- can't --
unless you can point me to a specific
document and help me here, I don't have a
recollection of it.

Q. All right. So sitting here
today, you are not aware that CVS ever
produced the DEA SOP --

A. I --

MR. BOGLE: Wait until he
finishes.

BY MR. HYNES:

Q. -- to DEA.

MR. HYNES: Thanks.

MR. BOGLE: Object to form.

1 You can answer.

2 THE WITNESS: Again, I

3 don't.

4 BY MR. HYNES:

5 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

21 opinion whatsoever at the moment.

22 BY MR. HYNES:

23 Q. I want to turn your

24 attention to Page 170 of your report.

1 A. I'm there.

2 Q. Last paragraph, first
3 sentence, you state that -- and this
4 relates to the PDMR reports. Do you
5 remember those?

6 A. I do remember those.

7 Q. You state that, "The
8 reports" -- this is the first sentence of
9 the last paragraph -- "were deficient as
10 an SOM report."

11 Do you see that? Do you see
12 that, sir?

13 A. I do see that.

14 Q. Okay. And then going up
15 above the block quoted language, you say
16 CVS represented that PDMR reports were
17 part of the company's efforts to monitor
18 suspicious orders.

19 Do you see that?

20 A. I do see that.

21 Q. Can you tell me where CVS
22 said that?

23 A. I can't point to a specific
24 quote right at this moment. No.

1 Q. Let's look at the block
2 moment. And there you're quoting the
3 deposition testimony of Mark Vernazza.
4 Do you know who Mark Vernazza is?

5 A. Yes, I do know who Mark
6 Vernazza is.

7 Q. And who is he?

8 A. As I recall, he was counsel
9 for CVS. He was also the 30(b)(6)
10 witness.

11 Q. That's right. That's right.
12 So he was giving CVS's testimony, would
13 you agree with that, as a corporate
14 witness?

15 A. Yes.

16 [REDACTED]
[REDACTED]
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Q. Do you have any other reason to believe that the PDMR reports were SOM reports?

A. Actually, at the moment, I don't have a document that I can point to.

Q. Okay. We've talked a lot about the IRR, right?

A. We have talked a lot about the IRR.

Q. And would you agree that that's a SOM report?

1 A. I would say that the IRR is
2 a report of orders that have flagged to
3 be --

4 Q. Flagged orders as
5 potentially suspicious?

6 MR. BOGLE: Wait until he
7 finishes, Counsel.

8 Are you finished? Finish
9 your answer, and then he'll --

10 MR. HYNES: Sorry about
11 that.

12 THE WITNESS: Can you back
13 up and ask the question again?

14 BY MR. HYNES:

15 Q. Would you agree that the
16 IRRs were the report that CVS used to
17 evaluate whether orders were suspicious,
18 the report that CVS used in its SOM
19 program?

20 A. I would say it was a tool
21 that was used in the SOMs program. Yes.

22 Q. Would you agree that it's a
23 SOM report?

24 A. I think we're splitting

1 hairs. I would say it's closer to being
2 a SOMs report if it -- based on what I
3 know of the algorithm, but again I'm not
4 a --

5 Q. Closer than --

6 MR. BOGLE: Are you done?

7 THE WITNESS: Because of the
8 complexity of the algorithm and
9 all of the factors that I saw, no,
10 I did not understand the math.
11 But I'm not a mathematician. I'm
12 not sure. So it's pretty
13 complicated. It looked, at least
14 on its face, based on my
15 understanding that it would be
16 closer to a SOMs report in the
17 sense that it was looking at
18 pattern and frequency and sizes,
19 well, from what I can tell.

20 BY MR. HYNES:

21 Q. And --

22 A. And scoring the order, and
23 then above a certain score, those orders
24 were then hitting the IRR as needing

1 further follow-up in due diligence.

2 Q. When you say closer to a SOM
3 report, you mean closer to the PDMR
4 report? Is that the comparison that
5 you're making?

6 A. I think that's the
7 comparison I'm drawing.

8 Q. Okay. Okay. And the last
9 sentence of that last paragraph, you
10 conclude that the PDMR reports were
11 ineffective anti-diversion control.

12 Do you see that statement?

13 A. I do see that statement.

14 Q. You are aware, aren't you,
15 Dr. Whitelaw, that those reports were one
16 of several tools that CVS used to prevent
17 diversion?

18 MR. BOGLE: Object to form.

19 THE WITNESS: Would you
20 clarify those reports?

21 BY MR. HYNES:

22 Q. The PDMR reports.

23 A. Which reports are you
24 talking about?

1 Q. The PDMR reports, those were
2 one of several reports that CVS used to
3 prevent diversion.

4 MR. BOGLE: Object to form.

5 THE WITNESS: I would
6 testify that that was the only
7 report that I saw that was even an
8 attempt at a suspicious order.
9 I'm not sure what you're referring
10 to. So can you help me here?

11 BY MR. HYNES:

12 Q. I'm just -- I'm just trying
13 to establish that the PDMR reports were
14 one of several reports that CVS used in
15 it's anti-diversion program. For
16 example, the IRR report is a different
17 report than the PDMR report and also was
18 used in an anti-diversion manner.

19 MR. BOGLE: Object to form.

20 BY MR. HYNES:

21 Q. Do you agree with that?

22 A. Yes, I agree.

23 Q. Okay. Sir, the PDMR
24 reports, did you review any of those?

1 A. Honestly, I can't remember
2 at this point.

3 Q. Can you tell me what they
4 looked at?

5 A. Again, I can't remember at
6 this point in time. I'm sorry.

7 Q. Do you know whether --

8 A. Do you have a document that
9 you would like me to look at?

10 Q. I don't. Do you know
11 whether they incorporated dispensing
12 data?

13 A. Again, I'd like to see the
14 report to be absolutely certain. I
15 don't -- I would be speculating.

16 Q. Well, you write on Page 170
17 that the reports compared orders made
18 with distribution centers to dispensing.
19 So does that refresh your recollection
20 that these reports incorporated
21 dispensing data?

22 MR. BOGLE: Can you tell me
23 exactly where you're looking at
24 here? I'm not seeing where you

1 are at. I'm not saying it's not
2 on here. I just don't see where
3 you're at.

4 MR. HYNES: I'm going to go
5 to a different part in this.

6 BY MR. HYNES:

7 Q. First paragraph under the
8 PDMR reports. Second to last sentence,
9 "Their reports that show how much was
10 shipped to and dispensed from a
11 pharmacy."

12 Do you see that?

13 A. I see it.

14 Q. Do you recall writing it?

15 A. I do recall writing it.

16 Q. Okay. So does that refresh
17 your recollection that these reports
18 incorporated dispensing data?

19 A. In some form or another they
20 incorporated dispensing data.

21 MR. BOGLE: Object to form.

22 THE VIDEOGRAPHER: If you
23 can just pull your mic down.

24 BY MR. HYNES:

1 Q. Sir, you state on Page 178,
2 so eight pages up. The first sentence
3 under Number 2, "Use of MicroStrategy."
4 Do you see that?

5 I'll give you some time to
6 get there.

7 A. I do see it.

8 Q. First sentence, second line,
9 you say that "Only tools" -- actually,
10 let me go back to the first line.

11 "Although it is not
12 completely clear, it appears that"...the
13 only tools available for the due
14 diligence follow-up prior to 2012 were
15 the PDMR (VIPER) reports."

16 Do you see that?

17 A. I do see that.

18 Q. And if you look at
19 Footnote 1018, you quote Mr. Mortelitti's
20 testimony.

21 A. I did.

22 Q. At Pages 67 to 68. But he
23 testified that he didn't know what the
24 field viper analyst had access to. Do

1 you remember reviewing that testimony?

2 A. I would need to see his
3 testimony again. And again it's --
4 you're asking me specifics about specific
5 testimony. If you have something to show
6 me, I will look at it.

7 Q. Well, my question for you --

8 A. This is not a memory test,
9 Paul.

10 Q. Understood. Understood. I
11 have limited time.

12 My question to you is, are
13 you aware of any other evidence in the
14 record indicating that the PDMR reports
15 were the only tools available for due
16 diligence prior to 2012?

17 A. And my answer would be I'm
18 not aware at --

19 Q. Okay.

20 A. -- without looking through
21 the report and his testimony.

22 Q. Thank you.

23 Yesterday you testified, and
24 I had the court reporter pull this for

1 me, and I can show it to you. This was
2 during Walgreens questioning.

3 You said, "Having reviewed
4 the documents, having asked for the
5 information, having looked at what they
6 were using to determine suspicious order
7 monitoring, based on my review, I did not
8 see them" -- and "them" you're referring
9 to CVS and Walgreens -- "using dispensing
10 data in their own -- to try to clear red
11 flags for various suspicious orders."

12 Do you remember giving
13 testimony yesterday that you did not see
14 any documents indicating that CVS and
15 Walgreens had used dispensing data to try
16 to clear red flags?

17 MR. BOGLE: Since you've got
18 it pulled, can you show him the
19 question and answer?

20 MR. HYNES: Yeah.

21 MR. BOGLE: The full
22 question and answer?

23 MR. HYNES: I've underlined
24 it right there.

1 THE WITNESS: I see it.

2 MR. HYNES: I'll take that

3 back. Thanks, Brandon.

4 BY MR. HYNES:

5 Q. On Page 178 of your report,
6 last paragraph, are you there?

7 A. I'm there.

8 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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Q. Okay. You --

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A. And --

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Q. Go ahead.

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MR. BOGLE: Go ahead.

10

THE WITNESS: If I wasn't

11

clear then, I'm trying to be clear

12

now.

13

BY MR. HYNES:

14

Q. Okay. So your testimony was

15

you had not seen any documents, any

16

documents that showed CVS or Walgreens

17

using dispensing data.

18

Is it your testimony today

19

that you have seen documents showing CVS

20

using dispensing data to clear red flags?

21

MR. BOGLE: Object to form.

22

THE WITNESS: I have seen

23

the availability of the tool. I

24

have not seen anywhere in the due

1 diligence files presented that you
2 were using prescription data. And
3 I know from the documents I
4 reviewed that you were only
5 looking at a handful of those
6 IRRs.

7 BY MR. HYNES:

8 Q. Did you ask counsel for due
9 diligence documents indicating whether
10 CVS used dispensing data to clear red
11 flags?

12 A. I believe I did.

13 Q. And you didn't receive any?

14 MR. BOGLE: Object to form.

15 THE WITNESS: Again, all
16 the -- all the documents I've
17 reviewed, I can't remember every
18 document I've reviewed.

19 BY MR. HYNES:

20 Q. Okay.

21 (Document marked for
22 identification as Exhibit
23 Whitelaw-19.)

24 BY MR. HYNES:

1 Q. This will be Exhibit
2 Whitelaw 19.

3 MR. HYNES: I put it on the
4 wrong one.

5 BY MR. HYNES:

6 Q. Here you go, Dr. Whitelaw.

7 A. Thanks.

8 MR. HYNES: Did you guys get
9 a copy?

10 MR. BOGLE: Yeah.

11 BY MR. HYNES:

12 Q. Sir, I'll give you a minute
13 to take a look at the document.

14 MR. BOGLE: Do you want him
15 to just let you know when he's
16 done?

17 MR. HYNES: Sure.

18 MR. BOGLE: Will that help
19 you?

20 MR. HYNES: Sure.

21 BY MR. HYNES:

22 Q. Ready, sir?

23 A. I'm ready.

24 Q. Sir, this is a document that

1 your counsel Mr. Goetz used at the
2 deposition of Aaron Burtner. Do you
3 recall seeing this document?

4 A. I can go to my reliance
5 list, but I don't recall it off the top
6 of my head.

7 Q. Did you review Mr. Burtner's
8 deposition transcript in its entirety?

9 A. Again, I don't recall that I
10 reviewed Mr. Burtner's testimony in its
11 entirety or not.

12 Q. Okay. And then sitting
13 back, when you reviewed a deposition,
14 would you -- transcript, would you also
15 review the exhibits?

16 A. Yes.

17 Q. Sir, this is an e-mail dated
18 February 7, 2014, from Shauna Helfrich.

19 Do you see that on the first
20 page?

21 A. I do.

22 [REDACTED]
[REDACTED]
[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(Document marked for

identification as Exhibit

Whitelaw-20.)

BY MR. HYNES:

Q. We'll mark this as Whitelaw
20.

MR. HYNES: That's for him.

And this one is for you gentlemen.

BY MR. HYNES:

Q. Dr. Whitelaw, to save you a
little bit of time. I just want to ask
you about the first page and the last
page.

A. Let me just go through the
whole document. But I appreciate you
trying to save me some time.

I see it.

Q. This is a document that
Mr. Goetz used during the deposition of
Gary Milikan. Do you recall reviewing

1 this document before today?

2 A. I do not recall, but I can
3 go and check the reliance list if you
4 would like.

5 Q. That's not necessary.

6 You see the date of the
7 document, December 10, 2013, on the first
8 page?

9 A. I do see that document.

10 Q. Okay.

11 A. Or I'm sorry -- that date.

12 Pardon me.

13 Q. You see it's from Shauna
14 Helfrich?

15 A. I see it's from Shauna
16 Helfrich.

17 [REDACTED]

[REDACTED]

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Q. Okay. Thank you. Let's
turn to Page 179.

The last paragraph, you say,
"Delivered at the end of 2012, AGI Store
Metrics was the successor program to the
MicroStrategy tool."

Do you see that?

And do you remember what the

1 Store Metrics were?

2 A. Yes, I do remember what the
3 Store Metrics were. And I do remember
4 writing this sentence. And I do remember
5 reading this document.

6 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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Q. Okay. Sir, you're also

1 aware that the outside vendors had their
2 own SOM systems?

3 A. I am aware that they had own
4 SOM systems.

5 Q. Just turn back a page to
6 Page 181.

7 A. Mm-hmm.

8 Q. You have a table there. And
9 it's titled "Summary of Aaron Burtner LP
10 Analyst Time Studies (June-July 2012)."

11 Do you see that?

12 A. I do.

13 Q. And right above that, you
14 write, "Below is a chart showing a
15 representative 12 days in 2012 which
16 demonstrates how few orders were sent for
17 investigation across Mr. Burtner's five
18 distribution centers."

19 Do you see that?

20 A. I do.

21 Q. Okay. First, you say
22 Mr. Burtner's five distribution centers.
23 So you are aware at the time that CVS had
24 about ten distribution centers that

1 were -- that were distributing controlled
2 substances to CVS retail pharmacies?

3 A. I am.

4 Q. And that Mr. Burtner
5 reviewed the IRR for half of those
6 distribution centers?

7 A. Well, if there were ten, as
8 you represent, yes. Five is half of ten.
9 So, yes.

10 Q. Okay. And then you say a
11 representative 12 days. Did you choose
12 those 12 days that you put in here.
13 When?

14 And I say that, did you
15 choose the time studies for those --
16 these 12 days?

17 A. Did I choose the time
18 studies? I pulled this from an exhibit,
19 a -- a deposition exhibit from
20 Mr. Burtner. So I believe they were
21 already chosen for his deposition. I was
22 pulling the actual exhibit.

23 Q. Okay. So --

24 A. And the exhibit is listed

1 here. I pulled these studies, yes.

2 Q. Okay.

3 A. I asked for them.

4 Q. And these were all the ones
5 that were used in his deposition,
6 correct?

7 A. Yes. To the best of my
8 knowledge.

9 Q. So these are the ones that
10 the plaintiffs' counsel selected to use
11 in his deposition?

12 A. I believe that is an
13 accurate representation.

14 Q. And Mr. Goetz did that
15 deposition, right?

16 A. I don't know who -- I don't
17 recall who was at that deposition.

18 Q. Okay. Did you review time
19 studies for any other day besides these
20 12 days?

21 A. I honestly can't recall. I
22 honestly don't remember.

23 Q. So can you tell me what
24 makes these 12 a representative sample?

1 A. Other than being a
2 representative sample of a certain period
3 in time, they are just a sample.

4 Q. So you don't know how these
5 12 were selected from the broader
6 collection of time studies?

7 A. I don't recall.

8 Q. So it's possible that you --
9 you might have selected these 12 from the
10 larger category?

11 MR. BOGLE: Object to form.

12 THE WITNESS: Again, as I
13 said to you, I asked for time
14 studies and I reviewed those time
15 studies. Now I'm trying to
16 remember -- I don't remember how
17 I -- exactly how they ended up in
18 the table that I put together, I'm
19 sorry.

20 BY MR. HYNES:

21 Q. No, no, that's fair. That's
22 fair.

23 A. At this point I can't get
24 you there.

1 Q. If you don't recall, you
2 don't recall.

3 A. I don't recall.

4 Q. Did you review the IRRs
5 related to these time studies?

6 A. Again, I don't recall.

7 Q. So you don't know how many
8 pages the IRRs were --

9 MR. BOGLE: Object to form.

10 BY MR. HYNES:

11 Q. -- that these time studies
12 relate to?

13 MR. BOGLE: Object to form.

14 THE WITNESS: Again, as I
15 said, I don't recall.

16 BY MR. HYNES:

17 Q. Okay. You don't know how
18 many total orders are reflected in those
19 IRRs?

20 MR. BOGLE: Object to form.

21 THE WITNESS: Again, I don't
22 recall.

23 BY MR. HYNES:

24 Q. Okay. Do you think at any

1 point in time you knew?

2 A. I'm afraid I can't answer
3 your question. I don't recall.

4 Q. Did you make an attempt to
5 investigate the IRRs that these time
6 studies relate to?

7 A. I'm sure I did. I don't
8 recall specifically. So you're asking me
9 to speculate. I don't -- I don't have a
10 list of everything I looked at or
11 everything I -- haven't -- you know,
12 below.

13 But yes, I normally would
14 have tried to look for additional data.
15 But I don't -- can't tell you
16 specifically, I'm sorry.

17 Q. If you had looked at them,
18 would they be cited in your report?

19 A. Again, if they were relevant
20 to the report I would have cited them.
21 They certainly would have been in the
22 reliance list.

23 MR. HYNES: All right. I'll
24 pass the witness. And I'll just

1 state on the record as other
2 defendants have said: I do have a
3 lot more questions for you. My
4 time is limited. So I do reserve
5 my right to seek more time. Thank
6 you for your time today.

7 THE VIDEOGRAPHER: Going off
8 the record. The time is 2:14 p.m.

9 (Short break.)

10 THE VIDEOGRAPHER: We are
11 back on the record at 2:29 p.m.

12 - - -

13 EXAMINATION

14 - - -

15 BY MR. DAVISON:

16 Q. Good afternoon,
17 Dr. Whitelaw. My name is William
18 Davison. I represent Mallinckrodt in
19 this matter, which is one of the entities
20 that you wrote your report on.

21 As we're getting towards the
22 end of the day and it's Friday night, I'm
23 going to try and help make this as
24 efficient as possible.

1 So I'm going to mark
2 Exhibit 21, which is simply another copy
3 of your appendix of materials considered.
4 I'm hopeful that way we won't have to be
5 flipping back and forth as we're looking
6 at things as we go through. Does that
7 make sense to you?

8 A. That does make sense to me.

9 Q. All right. We'll try and
10 save some time.

11 (Document marked for
12 identification as Exhibit
13 Whitelaw-21.)

14 BY MR. DAVISON:

15 Q. So, Dr. Whitelaw, a few
16 clarifying questions that I wanted to
17 talk to you about with respect to your
18 qualifications.

19 As you mentioned yesterday
20 that you have past compliance experience
21 in designing sample programs for
22 noncontrolled substances, correct?

23 A. That is what I said, yes.

24 Q. And you testified that these

1 sample programs involved the delivery of
2 samples to healthcare professionals, like
3 physicians, nurse practitioners, and
4 physician assistants; is that correct?

5 A. Yeah, that's what I said.

6 Q. You testified that this was
7 delivered by sales representatives to
8 those healthcare professionals, correct?

9 A. On the sample -- on the
10 programs I worked on, yes.

11 Q. And so just to confirm, your
12 compliance work there was helping to
13 establish a compliant procedure for the
14 sales representatives to provide samples
15 to healthcare providers.

16 A. No. I think that
17 underrepresents the work that I did. It
18 wasn't just a procedure. It was a
19 process. And to also investigate
20 outliers, to investigate data as it came
21 up, to the -- the equivalent of what
22 we've been talking about all day is due
23 diligence. But due diligence on the
24 sample side, et cetera. So it was

1 working on the entire process, not just a
2 procedure.

3 Q. Fair enough. So it's
4 broader than a procedure. And I guess my
5 question was more focused. One of the
6 goals of the processes that you were
7 creating was to ensure that there was a
8 compliant way for sales representatives
9 to provide the samples to healthcare
10 providers, correct?

11 A. Yes, including preventing --
12 obviously the goal being to prevent
13 samples going astray, a/k/a diversion.

14 Q. Of course. And in designing
15 this compliance program, did you consult
16 OIG guidance?

17 A. I'm sure I did.

18 Q. And you would have consulted
19 OIG advisory opinions?

20 A. I would have consulted any
21 relevant guidance at the time, yes.

22 Q. That could include corporate
23 integrity agreements?

24 A. It could.

1 Q. And would it include
2 settlements?

3 A. It could.

4 Q. And, sir, speaking of OIG,
5 are you aware that the OIG provided
6 guidance for compliance programs for
7 physicians in 2000?

8 A. Yes, I am.

9 Q. Did you consult it for the
10 sample programs that you would have --
11 the sample compliance programs that you
12 would have designed?

13 A. Honestly I don't remember
14 everything that I looked at at that time.
15 It's been a while.

16 Q. Okay. Did you consult this
17 when you wrote your report?

18 A. I'm sorry.

19 Q. By this -- apologies.

20 A. Please.

21 Q. Did you consult the OIG
22 guidance for compliance programs for
23 physicians dated from 2000 in writing
24 your report?

1 A. I did look at it. It's
2 footnoted in my report. So obviously I
3 did look through it and look at it, yes.

4 Q. All right. So the
5 compliance program for physicians is
6 footnoted in your report is your
7 recollection?

8 A. It is.

9 Q. Okay. Thank you. Now, you
10 stated just a little while ago to
11 Mr. Hynes that you've never operated or
12 audited a suspicious order monitoring
13 system; is that correct?

14 A. That is what I told him,
15 yes.

16 Q. Okay. Do you consider
17 yourself an expert on suspicious order
18 monitoring?

19 A. I believe, based on the work
20 that I have done, my 30 years'
21 experience, all that I have reviewed, all
22 the DEA guidance I have reviewed, my
23 conversations with Mr. Rafalski, yes, I
24 would say that I am qualified to be a

1 SOMs expert.

2 Q. And prior to your
3 discussions with Mr. Rafalski, all of the
4 documents that you reviewed for this
5 litigation, all of the deposition
6 transcripts, all of that work that you
7 did for this litigation, would you have
8 considered yourself a suspicious order
9 monitoring expert?

10 MR. BOGLE: Object to form.

11 THE WITNESS: Could you be
12 more -- again, could you repeat
13 the question? I'm sorry. It's
14 been a long day.

15 BY MR. DAVISON:

16 Q. Understood, sir. So prior
17 to the work that you did for this
18 litigation, which we've discussed
19 included reviewing, you know, hundreds of
20 thousands of documents, deposition
21 transcripts, discussions with
22 Mr. Rafalski, did you consider yourself a
23 suspicious order monitoring expert?

24 MR. BOGLE: Same objection.

1 THE WITNESS: Honestly, I
2 don't rightly recall if I ever
3 thought of it in those terms.

4 BY MR. DAVISON:

5 Q. So your answer is that you
6 never really thought about it one way or
7 another --

8 A. I'm a compliance expert.

9 Q. -- whether you were a
10 suspicious order monitoring -- excuse me.
11 Sorry.

12 A. Sorry.

13 Q. She's going to -- it's late
14 for her as well, so.

15 A. Apologies.

16 Q. No problem.

17 So you didn't think of it
18 one way or another as to whether you were
19 a suspicious order monitoring expert?

20 MR. BOGLE: Object to form.
21 Asked and answered.

22 THE WITNESS: As I said, I
23 don't recall. Again, I'm a
24 compliance expert. I work in a

1 variety of different areas. I'm
2 not sure that I reflected on it
3 the way you're asking me to.

4 BY MR. DAVISON:

5 Q. Okay. Prior to this
6 litigation, have you ever held yourself
7 out to a potential client as a suspicious
8 order monitoring expert?

9 A. Other than the work that I
10 did on a proposal for Deloitte, which,
11 again, was more of a compliance process
12 assessment for suspicious order
13 monitoring program, I don't recall ever
14 putting that moniker on my name.

15 Q. So you didn't tell Henry
16 Schein that you were an -- that you were
17 an expert in suspicious order monitoring
18 when you made that pitch, correct?

19 MR. BOGLE: Objection.

20 Misstates testimony.

21 THE WITNESS: As I said, I
22 think I answered your question as
23 best I can. I don't have anything
24 else to add to that answer.

1 BY MR. DAVISON:

2 Q. All right. So I think you
3 said, "I don't recall ever putting that
4 moniker on my name." Is that accurate?

5 MR. BOGLE: That's part of
6 his answer.

7 THE WITNESS: That was part
8 of my answer.

9 BY MR. DAVISON:

10 Q. Okay. Sir, you are
11 providing an opinion regarding the
12 relevant standards surrounding the
13 design, implementation, and operation of
14 corporate and controlled substances
15 compliance programs for the
16 pharmaceutical industry; is that correct?

17 A. Can you --

18 Q. If you want to look, I'm
19 on -- I'm on Page 2 --

20 A. Where are we?

21 Q. -- of your report. Just
22 taking what you say your scope is.

23 A. No, I know. I'm just asking
24 where you are. That's helpful for me.

1 Okay. Where are you now?

2 Q. I'm on Page 2. If you look
3 at Number 1 under scope.

4 A. Number 1 under scope, okay.

5 Q. So I'm going to repeat the
6 question. You were providing an opinion
7 regarding the relevant standards
8 surrounding the design, implementation
9 and operation of corporate and controlled
10 substances compliance programs for the
11 pharmaceutical industry; is that
12 accurate?

13 A. That's what it says.

14 Q. Was that what you are
15 providing an opinion on?

16 A. Yes.

17 Q. Okay. You were also
18 providing an opinion regarding the
19 application of those standards to
20 manufacturers and distributors of
21 controlled substances, correct?

22 A. That is correct.

23 Q. You also are providing an
24 opinion on the effectiveness of the

1 compliance programs for five distributors
2 and one manufacturer of prescription
3 opioid medicinal products based upon
4 available documentation from 1996 to
5 2018, correct?

6 A. That is also correct.

7 Q. Did plaintiffs' counsel
8 select the five distributors and one
9 manufacturer on which you wrote your
10 report?

11 MR. BOGLE: Objection.

12 THE WITNESS: These were the
13 ones that they asked me to do a
14 review of, yes.

15 BY MR. DAVISON:

16 Q. The only manufacturer for
17 which you are providing an opinion on the
18 effectiveness of its compliance program
19 is Mallinckrodt, correct?

20 A. I was only asked to look at
21 Mallinckrodt.

22 Q. Well, sir, my question is a
23 little bit different. The only
24 manufacturer for which you are providing

1 an opinion on the effectiveness of its
2 compliance program is Mallinckrodt,
3 correct?

4 A. Mallinckrodt is the only
5 manufacturer in my report, sir.

6 Q. So the answer to that
7 question is yes?

8 A. The answer to that question
9 is yes.

10 Q. Thank you. You do not
11 intend to offer an opinion at this time
12 regarding any other manufacturer's
13 compliance program, correct?

14 A. Not at this time.

15 Q. You do not intend to offer
16 an opinion regarding the application of
17 your opinions regarding the standards
18 surrounding the design, implementation,
19 and operation of controlled substances
20 compliance programs to any other
21 manufacturers program at this time,
22 correct?

23 MR. BOGLE: Object to form.

24 BY MR. DAVISON:

1 Q. Do you want me to start
2 again?

3 A. Yeah, and read it a bit
4 slower or at least give me something to
5 look at it because that's an awful lot
6 of -- that's a whole mouthful of words.

7 Q. Let's -- we'll strike that
8 one.

9 You do not intend to offer
10 any opinions regarding any other
11 manufacturer defendant in this litigation
12 at this time, correct?

13 A. Not at this time.

14 Q. And there is nothing in your
15 report regarding any other manufacturer
16 of controlled substances other than
17 Mallinckrodt, correct?

18 MR. BOGLE: Object to form.

19 THE WITNESS: No, I think
20 that's inaccurate. There are a
21 couple references in my report to
22 Endo and Purdue up in the front of
23 the report.

24 BY MR. DAVISON:

1 Q. But you didn't review their
2 suspicious order monitoring program,
3 correct?

4 A. No. There's no review of
5 another manufacturer's suspicious order
6 monitoring program in my report.

7 Q. All right. So I think I
8 have an understanding of kind of the
9 opinions at a high level. I'd like to
10 discuss just a couple of questions
11 regarding opinions you're not offering.
12 Okay?

13 A. Sure.

14 Q. So you stated earlier today
15 that you're here as a compliance expert,
16 so you are not drawing legal conclusions,
17 correct?

18 A. Yes, sir, that is correct.

19 Q. So you're not offering a
20 legal conclusion as to whether any
21 defendant violated the Controlled
22 Substances Act, correct?

23 A. That is correct.

24 Q. You are not offering a legal

1 conclusion as to whether any defendant
2 violated the SOM regulation?

3 A. Correct.

4 Q. And when you were questioned
5 earlier today by Cardinal's counsel, you
6 stated that the question of whether any
7 of Cardinal's products were diverted was
8 outside the scope of your report.

9 Is the same true for
10 Mallinckrodt's products?

11 A. The same holds true for
12 Mallinckrodt, yes.

13 Q. And is the same true for all
14 of the distributors and manufacturers in
15 your report's box?

16 A. Could you give me the
17 question again, please?

18 Q. Yes. No problem.
19 Understood.

20 With respect to Cardinal
21 earlier today, you stated that the
22 question of whether any product was
23 diverted was outside the scope of your
24 report. Is the same true for all of the

1 distributors, pharmacies and
2 manufacturers that you reviewed?

3 A. Again, as I said, same thing
4 for Cardinal I would say for every other
5 defendant is the same. I looked at the
6 policies and the process and the systems,
7 and that is what I'm rendering my -- my
8 opinions on.

9 Q. So the answer to that is
10 yes?

11 A. The answer to that is I'm
12 not making statements about whether any
13 particular order was diverted or not
14 diverted.

15 Q. Thank you, sir.

16 Now, sir, in evaluating the
17 effectiveness of Mallinckrodt's
18 compliance program, you utilized the
19 methodology that have used -- that you
20 have used during the last 30 years when
21 auditing or investigating compliance
22 issues; is that correct?

23 A. I think that's a fair way of
24 characterizing it, yes.

1 Q. So I want to -- I want to
2 understand a little bit more about the
3 methodology that you've used in your
4 30 years of experience.

5 A. Sure.

6 Q. What is your practice
7 generally when you select data or
8 documents for a sample?

9 MR. BOGLE: Object to form.
10 Vague and ambiguous.

11 BY MR. DAVISON:

12 Q. Let me see if I can narrow
13 it down for you. I'll withdraw that
14 question.

15 A. That would be real helpful.

16 Q. No problem.

17 Generally in your
18 experience, when you're selecting data or
19 documents to review, do you do a random
20 sample?

21 MR. BOGLE: Object to form.

22 THE WITNESS: You're still
23 going to have to narrow it down
24 further.

1 BY MR. DAVISON:

2 Q. Are you familiar with OIG
3 toolkits and resources like RAT-STATS to
4 select random samples?

5 A. I am familiar with what
6 those are, yes.

7 Q. Okay. And that's a way to
8 select random samples of data or
9 documents for review, correct?

10 A. But it's not a way of
11 utilizing and looking at process systems
12 and process and controls for compliance
13 programs, per se. That's not how we
14 do -- that's not how I do that, no.

15 Q. So when you're looking at
16 processes and controls for compliance
17 programs, you do not use random sampling?

18 A. No. I actually ask you what
19 the standards are that you're doing and
20 how are you working against those
21 standard and show me how those are
22 actually working.

23 Q. Okay. So talking about what
24 you specifically reviewed today and as

1 part of your methodology. It's fair to
2 say that you reviewed a number of
3 standard operating procedures; is that
4 correct?

5 A. I reviewed a number of
6 documents that were supposed -- that were
7 purported to be standard operating
8 procedures or draft standard operating
9 procedures, yes.

10 Q. And you also reviewed
11 e-mails for each of the individual
12 manufacturers, distributors, pharmacies,
13 that you looked at, internal e-mails?

14 A. E-mails were part of it.

15 Q. And generally, in your
16 compliance history, one way of gaining
17 information would be to interview
18 employees of a client, correct?

19 A. That is one way to do it,
20 yes.

21 Q. And -- and here I understand
22 there weren't interviews, but you
23 reviewed deposition transcripts. Is that
24 fair?

1 A. That is fair. But in the
2 same way that I interviewed, just so we
3 are completely clear, that I would have
4 interviewed Mallinckrodt employees if I
5 were working -- Mallinckrodt was my
6 direct client. I worked through
7 plaintiffs and plaintiffs' counsel and
8 interviewed them the same way, saying
9 this is what I'm looking for, these are
10 the documents I need to do my review,
11 this is what I'm looking for.

12 It's the same kind of
13 conversation. When I got them, review
14 them, and I look at them and, you know,
15 again, ask for clarifying questions, ask
16 for clarifying documents, et cetera. So
17 it's the same methodology.

18 Q. All right. So generally the
19 same methodology. And -- and another
20 piece that -- that you'd review would be
21 correspondence with regulatory or
22 government agencies, correct?

23 A. That is correct.

24 Q. All right. And you'd agree

1 with me that all of these pieces are
2 important when you're evaluating the
3 compliance program of a client?

4 A. I would say all the -- all
5 the general categories of documents we
6 are talking about are important, yes.

7 Q. So for example, you can't
8 just review a company's standard
9 operating procedures, because you
10 wouldn't know how the standard operating
11 procedures were being applied?

12 A. I would say that's an
13 accurate statement. You're looking for
14 not only what did you write down, but
15 what are you doing in practice.

16 Q. So reviewing standard
17 operating procedures alone wouldn't be
18 sufficient to draw a conclusion relating
19 to a client's compliance program?

20 A. Well, it would certainly be
21 sufficient to draw a conclusion about a
22 complying -- compliance program's written
23 standards section, yes. If you're asking
24 me do I think it's sufficient to draw

1 about an entire compliance program, no.

2 I think you need to look at more.

3 Q. And with respect to the work
4 that you did here, which is to look, as I
5 understand, at the anti-diversion
6 compliance programs for the -- the
7 defendants at issue here, it wouldn't be
8 sufficient, correct?

9 MR. BOGLE: Object to form.

10 THE WITNESS: It wouldn't be
11 sufficient. Could you be clear
12 what you mean by "it"?

13 BY MR. DAVISON:

14 Q. Solely reviewing standard
15 operating procedures.

16 MR. BOGLE: Object to form.

17 THE WITNESS: Again, we're
18 talking about a type of compliance
19 program. So the same way of doing
20 it and same document -- types of
21 documents you would be looking
22 for. It'd almost translate all
23 the way down the line as we've
24 discussed, we'd be looking at it

1 in the same way.

2 BY MR. DAVISON:

3 Q. So I -- I think your answer
4 was that solely reviewing standard
5 operating procedures would not be
6 sufficient alone.

7 MR. BOGLE: Object to form.

8 THE WITNESS: Would --
9 again, to -- to be precise, would
10 not be sufficient alone to judge
11 the entire program. But is
12 sufficient to judge the written
13 standard section of the program,
14 yes.

15 BY MR. DAVISON:

16 Q. Dr. Whitelaw, you mentioned,
17 I think multiple times, and I apologize
18 for bringing this back up. But you had
19 consulted with James Rafalski in writing
20 your report, correct?

21 A. That is what I've stated.

22 Q. So I do have a couple of
23 individual questions for Mallinckrodt.

24 Did you and Mr. Rafalski

1 discuss any specific topics or issues
2 related to Mallinckrodt?

3 A. No, not that I recall. I do
4 not believe we talked about Mallinckrodt
5 at all.

6 Q. So you didn't discuss with
7 Mr. Rafalski the DEA's investigation of
8 Mallinckrodt's SOM program?

9 A. No, sir. We did not talk
10 about that. We talked in general
11 terms -- so we can be clear. He and I
12 had general conversations about a
13 manufacturer's SOMs program. And sort of
14 a discussion around, you know, discussing
15 the distributor's program and a
16 manufacturer's program, how DEA looks at
17 them, you know, each one, a general
18 approach. But we did not get into the
19 specifics --

20 Q. Was --

21 A. -- regarding Mallinckrodt.

22 Q. Excuse me. I apologize.

23 A. We did not get into
24 specifics regarding Mallinckrodt.

1 Q. Was Mr. Rafalski aware that
2 the only manufacturer for which you are
3 conducting a review was Mallinckrodt?

4 A. I have no idea what he --
5 what he was aware of not aware of.

6 Q. Did Mr. Rafalski suggest any
7 particular Mallinckrodt documents that
8 you should review?

9 MR. BOGLE: Object to form.

10 THE WITNESS: Again, I think
11 I tried to make it as clear as I
12 can. We did not discuss
13 Mallinckrodt in specifics at all.
14 We talked about manufacturers'
15 SOMs programs and distributor SOMs
16 programs to the best of my
17 recollection.

18 BY MR. DAVISON:

19 Q. All right. So, sir,
20 yesterday you talked about the closed
21 system of distribution for controlled
22 substances, correct?

23 A. We touched on it, yes.

24 Q. All right. Would you agree

1 with me that generally a controlled
2 substance travels through that system
3 from a manufacturer to a distributor or
4 wholesaler, then to the pharmacy, and
5 then it's to the patient based on a
6 prescription by a physician?

7 A. Generally, the only caveat
8 that I would add is by someone licensed
9 to prescribe a controlled substance. And
10 let's be clear, it can be more than a
11 physician.

12 Q. Fair enough. And, sir, are
13 you aware that manufacturer registrants
14 generally sell their product to
15 wholesalers, distributors, or to
16 distributing chain pharmacies?

17 A. In general, yes.

18 Q. What do you mean by in
19 general, sir?

20 A. I'm sure there are
21 exceptions. You said -- you asked me,
22 was I generally aware. I answered your
23 question.

24 Q. All right. So would you

1 agree with me that generally a
2 manufacturer doesn't sell to individual
3 pharmacies?

4 A. Only indirectly. If you're
5 saying from the wholesaler to the
6 pharmacy, your product travels down that
7 pipeline, that I would say is a general
8 statement.

9 Q. Okay. So you said only
10 indirectly. I guess I just want to make
11 this clear. A manufacturer sells to the
12 wholesaler, correct?

13 A. Right. That's what I mean
14 by indirect.

15 Q. But they are not selling it
16 to the pharmacy?

17 A. They're selling it to the
18 wholesaler who's then in turn filling the
19 orders coming from the pharmacy. That
20 was the discussion that we just had, yes.

21 Q. Okay. Correct. I was just
22 trying to be clear on the selling
23 indirectly, what you mean by that?

24 A. That's what I meant by that.

1 Q. Okay. Sir, I'm going to
2 turn to Page 36 of your report.

3 A. Of course.

4 Q. Thank you. If you look at
5 Section B of your report.

6 A. Mm-hmm.

7 Q. You write, "For a
8 manufacturer's anti-diversion program, I
9 would expect to see."

10 Did I read that correctly?

11 A. You did.

12 Q. All right. And you list
13 four separate headings with some
14 sub-bullets underneath them, correct?

15 A. Yes, actually, I did.

16 Q. And, sir, there's no
17 citations in this section of your report,
18 correct?

19 MR. BOGLE: Objection.

20 Asked and answered previously.

21 But you can answer again.

22 THE WITNESS: There are no
23 footnotes here, no.

24 BY MR. DAVISON:

1 Q. And you said earlier that
2 generally if there was a document that
3 supported your proposition, you would
4 footnote it in your report, correct?

5 MR. BOGLE: Object to form.

6 THE WITNESS: Again, I'm
7 still not sure what -- I did
8 not -- there are no footnotes
9 here, if that's what you're asking
10 me. There are no footnotes right
11 here.

12 BY MR. DAVISON:

13 Q. So going through these,
14 you're not claiming that each of these
15 expectations that you've laid out here is
16 something that's explicitly stated within
17 the Controlled Substances Act, correct?

18 (Brief interruption.)

19 BY MR. DAVISON:

20 Q. I'll repeat the question for
21 you.

22 A. Thank you.

23 Q. So going through each of
24 these expectations, it's not something

1 that's explicitly stated within the
2 Controlled Substances Act, correct?

3 MR. BOGLE: Object to form.

4 THE WITNESS: Either that --
5 again, I need you to be more
6 clear, because as far as I'm
7 concerned, what I would expect to
8 see for a good compliance program
9 in this area, an anti-diversion
10 program, and these attributes are
11 what I see is embedded in the
12 overall concept of having an
13 effective -- an effective
14 anti-diversion program. So...

15 BY MR. DAVISON:

16 Q. And so that's why I said
17 explicitly. So I understand your view is
18 that these are implicit in having
19 effective controls against diversion,
20 those four words.

21 It's not explicitly listed
22 that a manufacturer must know their
23 customer within that statute, correct?

24 MR. BOGLE: Object to form.

1 THE WITNESS: If you're
2 asking me are those words in the
3 statute? Is that the question?

4 BY MR. DAVISON:

5 Q. That's what I'm asking you.
6 Yes.

7 A. No, they're not.

8 Q. Okay. And if any of the
9 words that are here under your
10 expectations were in the Controlled
11 Substances Act statute, you would have
12 cited to it, correct?

13 MR. BOGLE: Objection to
14 form.

15 THE WITNESS: It would have
16 been cited somewhere in the
17 report, yes.

18 BY MR. DAVISON:

19 Q. Well, generally good
20 scholarship is to cite to what you're
21 actually -- within the report, correct?

22 MR. BOGLE: Object to form.

23 THE WITNESS: And if you
24 note it, I do cite by section.

1 And then you'll notice there are
2 discussions before each of the
3 sections of attributes, which is
4 how it was organized. And I
5 believe we did have that
6 discussion yesterday.

7 BY MR. DAVISON:

8 Q. Yeah, I'm referring to a
9 separate section. No one talked about
10 this section yesterday.

11 A. I understand that. I'm
12 saying the way this whole part of the
13 report was organized, there is a general
14 discussion up front, the citations, and
15 then there are the attributes that are
16 listed. And there are not -- as we have
17 covered, there are not footnotes here.

18 Q. So I can go back to the
19 earlier sections in your report and I'll
20 find where these expectations come from,
21 correct?

22 A. You will see where those
23 concepts and expectations come from.

24 Q. Got it. And that's based on

1 your review of the guidance, your
2 experience, and your review of all the
3 documents that we've been discussing for
4 the past two days?

5 A. Correct. And my
6 conversation with Mr. Rafalski, et
7 cetera. It's the whole kit and caboodle.

8 Q. All right. I'm going to
9 understand these -- because we don't have
10 anything specific, I'm just going to call
11 these Dr. Whitelaw's expectations for a
12 good program. All right?

13 Starting with "know your
14 customer," you write, "The manufacturer
15 has and retains current granular and
16 specific knowledge about each distributor
17 of its controlled substance and their
18 unique circumstances including all the
19 information outlined in the distributor
20 section."

21 And then you state, "The
22 manufacturers should conduct distributor
23 site visits to review the distributors'
24 anti-diversion controls," correct?

1 A. Yes. That's what I say.

2 Q. And again, this is based on
3 all of the pages that lead up to Page 36,
4 correct?

5 MR. BOGLE: Object to form.

6 THE WITNESS: That, plus my
7 expectation, plus my discussions
8 with Mr. Rafalski, plus my review
9 of all the documents in this case.

10 BY MR. DAVISON:

11 Q. Sir, have you seen -- strike
12 that.

13 You're aware that DEA
14 conducts audits of distributors, correct?

15 A. Yes, I'm aware of that.

16 Q. All right. And that DEA
17 reviews distributors' SOM programs,
18 correct?

19 MR. BOGLE: Object to form.

20 THE WITNESS: Yes, I'm aware
21 of that as well.

22 BY MR. DAVISON:

23 Q. And that DEA reviews
24 distributors' anti-diversion controls?

1 A. From time to time, yes.

2 Q. All right. So

3 Dr. Whitelaw's expectation is that
4 manufacturers conduct reviews and audits
5 of distributors on top of what DEA does,
6 correct?

7 MR. BOGLE: Object to form.

8 THE WITNESS: They -- they
9 are your customers. You should be
10 aware of what they are doing and
11 comfortable with the way they are
12 acting. That is just good
13 third-party management, which is
14 part of an effective compliance
15 program.

16 Again, when you go back to
17 the federal sentencing guidelines,
18 the front of the report, if we
19 really want to discuss it in
20 detail, yeah, my expectation was
21 that you manage your own third
22 parties as well and not just
23 simply rely on the DEA.

24 BY MR. DAVISON:

1 Q. And --

2 A. The DEA gives you a piece of
3 information and it's information that you
4 should take into account. But it
5 doesn't -- it doesn't extract
6 Mallinckrodt from the requirement that it
7 should go out and make sure that the
8 people that it's selling its products to
9 are behaving in a way it expects them to
10 behave.

11 Q. Your expectation, sir, is
12 that manufacturers will hold their
13 distributors to a higher standard than
14 what DEA does, correct?

15 MR. BOGLE: Object to form.
16 Misstates his testimony.

17 THE WITNESS: You are
18 completely misstating what I said.
19 I said I expect you to go out and
20 look at your customers for the
21 products that you're selling and
22 ensure yourself that you're
23 comfortable with the way they are
24 behaving since they are selling

1 your products. You have a duty to
2 oversee those people who you
3 contract with.

4 BY MR. DAVISON:

5 Q. All right, sir. So if DEA
6 audits a distributor, gives them a clean
7 audit, and a month later Mallinckrodt
8 audits the distributor, can Mallinckrodt
9 rely on the DEA's audit?

10 MR. BOGLE: Objection.

11 Vague. Ambiguous. Overly broad.

12 THE WITNESS: Would you like
13 to explain to me what you mean by
14 rely? Because that's a fairly
15 broad statement here.

16 BY MR. DAVISON:

17 Q. So, sir, when -- when you
18 advise clients, you don't tell them to
19 rely on what the government does?

20 MR. BOGLE: Objection.

21 THE WITNESS: I don't know
22 what you mean by rely. Could you
23 please be clearer?

24 MR. DAVISON: Strike -- move

1 to strike the question.

2 BY MR. DAVISON:

3 Q. All right. You also stated
4 that "manufacturers are to utilize where
5 appropriate information derived from
6 chargeback data," correct?

7 A. That is what I state here,
8 yes.

9 Q. All right. So, sir, what's
10 a chargeback?

11 A. Well, let's go to my report
12 and we can go pull the definition that I
13 used in my report, sir --

14 Q. Strike that question.

15 Sitting here today, without
16 looking at your report, can you tell me
17 what a chargeback is?

18 A. I think to be completely
19 clear we should use the definition that's
20 in my report. And we can go to that, and
21 that's the definition I'm using.

22 Q. So, sir, your answer is no?

23 MR. BOGLE: Objection.

24 Misstates his testimony.

1 THE WITNESS: I said I'd
2 like to go and use the definition
3 that I have in my report and make
4 it completely accurate for the
5 record.

6 BY MR. DAVISON:

7 Q. So, sir, you are concerned
8 that you cannot provide me with an
9 accurate definition of a chargeback
10 without looking at your report, correct?

11 MR. BOGLE: Objection.
12 Misstates testimony.

13 THE WITNESS: That's not
14 what I'm saying.

15 BY MR. DAVISON:

16 Q. So sitting here today,
17 without looking at your report, what is a
18 chargeback?

19 A. As I said to you, I'm going
20 to go to my -- refer to my report and
21 tell you the definition that was used --
22 that I used in this report.

23 Q. All right. Since you can't
24 tell me about it, why don't we go to your

1 report. Tell me what the chargeback is.

2 MR. BOGLE: That's not what
3 he said.

4 Go ahead, go to your report.

5 THE WITNESS: Okay. We
6 will.

7 The definition that I'm
8 using for chargeback is on
9 Page 233.

10 BY MR. DAVISON:

11 Q. Okay. So what's the
12 definition?

13 A. Chargebacks are basically --
14 "Chargebacks are a common pharmaceutical
15 tool used by manufacturers to make
16 distributors whole when they sell
17 pharmaceuticals to pharmacies at prices
18 below what the distributor paid to the
19 manufacturer."

20 Q. And, sir, have you ever
21 reviewed chargeback data in your 30 years
22 of experience?

23 A. To my knowledge, I honestly
24 don't remember. I've reviewed a lot of

1 data over my 30 years' experience. So I
2 can't tell you whether or not I -- I
3 can't tell you.

4 Q. Sir, prior to your
5 engagement for this litigation, did you
6 know what a chargeback was?

7 A. Yes, I knew what a
8 chargeback was before this.

9 Q. You are aware that
10 chargeback data provides a limited subset
11 of information, correct?

12 MR. BOGLE: Object to form.

13 THE WITNESS: Can you define
14 what you mean by "limited subset
15 of information"?

16 BY MR. DAVISON:

17 Q. Sure. It provides a limited
18 amount of information relating the actual
19 sale of the product from the distributor
20 to the pharmacy.

21 A. I understand it provides
22 information about that.

23 Q. What information does it
24 provide?

1 A. Do we need to go into
2 every -- you know where the product --
3 you know where the wholesaler is selling,
4 and the amounts that are being sold to a
5 particular pharmacy, and you know what
6 the cost basis is and it's coming back to
7 you. So you know where your product is
8 going at the end of the day.

9 Q. Does Mallinckrodt receive
10 chargeback data for every sale that a
11 distributor makes to a pharmacy?

12 A. No, I don't believe it does.

13 Q. And sir, just to be clear,
14 the term "chargeback" is not used in the
15 Controlled Substances Act -- excuse me.
16 Strike that.

17 The term "chargeback" is not
18 used in the anti-diversion piece of the
19 Controlled Substances Act, correct?

20 A. It is not -- those
21 specific -- that specific term or
22 specific words are not used.

23 Q. So again, your view that a
24 manufacturer needs to look at chargeback

1 data comes from your reading of the
2 obligation to maintain effective controls
3 against diversion, is that fair?

4 A. It comes from my reading.
5 It also comes from the administrator's
6 position in -- in the Masters case and
7 others, that if you have information that
8 is potentially useful in operating your
9 suspicious order monitoring program, you
10 should be using that information.
11 Chargeback data is a piece of information
12 that you have access to that you should
13 be utilizing.

14 Q. And just to be clear, you're
15 not claiming that the Masters decision
16 stated anything about chargebacks, you're
17 instead broadening it out to include
18 chargebacks?

19 MR. BOGLE: Object to form.

20 THE WITNESS: I'm broadening
21 it out to describe what the
22 administrator, my reading of the
23 administrator's opinion was. That
24 if you have information that bears

1 on diversion, a manufacturer in
2 this case, cannot turn a blind eye
3 to that information, but should
4 utilize that information to the
5 extent possible.

6 BY MR. DAVISON:

7 Q. And, sir, in your 30 years
8 of experience, have you ever advised a
9 pharmaceutical manufacturer to utilize
10 chargeback data in its compliance
11 program?

12 A. Not for the areas that I was
13 looking at at the time, no. But if you
14 wanted it in general terms, I would have
15 advised them to use all available data.
16 I would tell any client to use all
17 available data that's pertinent to the
18 topic we are talking about.

19 MR. DAVISON: Move to strike
20 everything following "I was
21 looking at the time, no."

22 BY MR. DAVISON:

23 Q. Sir, we've -- people have
24 talked with you about the DEA witnesses

1 that have provided testimony in this
2 case.

3 Do you recall that?

4 A. I recall that.

5 Q. All right. And sir, I think
6 you testified that you reviewed Kyle
7 Wright's deposition transcript.

8 Do you recall that?

9 A. I do recall that.

10 Q. Are you aware that
11 Mr. Wright stated that chargebacks play
12 no role in suspicious order monitoring?

13 MR. BOGLE: Object to form.

14 THE WITNESS: Again, I don't
15 recall it off the top of my head.
16 No, I don't. Do you have a
17 document that you would like me to
18 look at?

19 BY MR. DAVISON:

20 Q. Well, sir, if the DEA says
21 that the chargebacks play no role in
22 suspicious order monitoring, would that
23 affect your opinion at all?

24 MR. BOGLE: Object to form.

1 THE WITNESS: No, actually
2 it wouldn't affect my opinion at
3 all.

4 BY MR. DAVISON:

5 Q. Okay. Now, sir, did you
6 request from plaintiffs' counsel all
7 documents reflecting communications
8 between Mallinckrodt and DEA relating to
9 its suspicious order monitoring and
10 anti-diversion programs?

11 A. Yes, I believe I did.

12 Q. So your expectation is that
13 you've reviewed all the documents
14 reflecting communications between DEA and
15 Mallinckrodt regarding Mallinckrodt's SOM
16 and anti-diversion programs, correct?

17 MR. BOGLE: Object to form.

18 THE WITNESS: No, I think
19 you're overstating what I said.

20 I said -- you asked me did I
21 ask counsel for any -- for the DEA
22 correspondence. I said I did.

23 Then you turned it around
24 and said have I reviewed

1 everything. And the answer is,
2 well, I reviewed everything that
3 they would have had in their files
4 that they provided to me.

5 So if there's something that
6 you haven't given to plaintiffs'
7 counsel, there's no way I could
8 have reviewed that.

9 BY MR. DAVISON:

10 Q. That's completely fair, sir.
11 So let me try to be a little more clear
12 on that.

13 A. Okay.

14 Q. So your expectation is that
15 plaintiffs' counsel provided you with
16 everything in their files that reflected
17 communications between Mallinckrodt and
18 DEA regarding its suspicious order
19 monitoring and anti-diversion program?

20 A. That is my expectation.

21 (Document marked for
22 identification as Exhibit
23 Whitelaw-22.)

24 BY MR. DAVISON:

1 Q. Sir, I'm handing you what's
2 been marked as Exhibit 22.

3 A. Okay.

4 Q. Have you finished reviewing?

5 A. I have.

6 Q. Sir, do you recall seeing
7 this document?

8 A. Again, I've seen so many
9 documents. I'm going to go to the
10 reliance list and double-check it.

11 Q. Sir, I've looked. I don't
12 think it's in here. But go ahead and
13 double-check my looking.

14 And, sir, if it helps out, I
15 think the Mallinckrodt materials are Page
16 267, 268, and 269.

17 A. I don't see it on the list.

18 Q. Okay. So, sir, the e-mail
19 here reflects discussion over "know your
20 customer's customer." Are you familiar
21 with that term?

22 A. I am familiar with that
23 term.

24 Q. And what do you understand

1 "know your customer's customer" to mean
2 for a pharmaceutical manufacturer?

3 A. It means the pharmaceutical
4 manufacturer should understand who the
5 distributor is in fact selling to. In
6 your case, if we used your general case
7 that you provided earlier, to the
8 pharmacy.

9 Q. Thank you, sir.
10 And one way of looking at
11 that would be through chargeback data; is
12 that fair?

13 A. That is one piece of data
14 that would be useful, yes.

15 Q. Okay. Do you see here that
16 Eileen Spalding states that she had had a
17 conversation with DI Heather White? Do
18 you know who DI Heather White is?

19 A. I can only suppose she is a
20 diversion investigator, but I don't know
21 who she is personally, no.

22 Q. And that, "DI White had
23 stated that she had called NYC and no one
24 there, including Sue Baker, DPM, has

1 heard anything about know your customer's
2 customer and the regulations do not
3 reflect such a requirement."

4 Did I read that correctly?

5 A. I believe you did read that
6 correctly.

7 Q. So this is the DEA telling
8 Mallinckrodt that there's no regulatory
9 requirement to know their customer's
10 customer, correct?

11 MR. BOGLE: Object to form.
12 Misstates the document.

13 THE WITNESS: No, I actually
14 do not agree with you, because the
15 policy from the DEA comes from
16 corporate headquarters. As best I
17 can tell, without knowing DI
18 Heather White, she is a field
19 investigator.

20 And, therefore, she may have
21 stated this. All I can -- all I
22 can say is that's what the record
23 reflects, is that Ms. Spalding had
24 a conversation with Ms. White and

1 Ms. White said -- supposedly said
2 this.

3 But I can't say that that's
4 DEA's policy or -- without more.

5 This is a -- Mallinckrodt's
6 employee's recollection of a
7 conversation with a potential -- I
8 believe diversion investigator.
9 Whether or not it's an accurate
10 representation of the conversation
11 or not, I have no way of knowing.
12 I just know what's on the
13 document.

14 BY MR. DAVISON:

15 Q. Yeah, you haven't seen this
16 document because plaintiffs didn't
17 provide it to you, correct?

18 MR. BOGLE: Object to form.

19 THE WITNESS: I don't recall
20 seeing this document. But I can't
21 tell you why I didn't see the
22 document. I can't go any further
23 than that.

24 BY MR. DAVISON:

1 Q. All the documents that you
2 received to review for this case came
3 from plaintiffs' counsel, correct?

4 MR. BOGLE: Object to form.
5 Misstates his prior testimony.

6 BY MR. DAVISON:

7 Q. Strike that.

8 All of the Mallinckrodt
9 produced documents in this litigation
10 that you received came from plaintiffs'
11 counsel, correct?

12 A. That is correct.

13 Q. Did Mr. Rafalski tell you
14 that this was a requirement of the SOM
15 regulation?

16 A. Again --

17 Q. Strike that.

18 Did Mr. Rafalski tell you
19 that monitoring chargebacks was a
20 requirement of the Controlled Substances
21 Act?

22 A. Again, I don't rightly
23 recall our conversation around
24 chargebacks any more than it's a good

1 source of information to be used by a
2 prudent manufacturer to know their
3 customer's customer. Beyond that general
4 discussion, I don't recall the specifics.

5 Q. And sir, you testified
6 earlier that some of your understanding
7 that you used in this litigation
8 regarding the suspicious order monitoring
9 regulation, Controlled Substances Act,
10 came from Mr. Rafalski, correct?

11 MR. BOGLE: Object to form.

12 THE WITNESS: I testified
13 that I had conversations with
14 Mr. Rafalski about the Controlled
15 Substances Act and regulations and
16 how DEA operates, yes.

17 BY MR. DAVISON:

18 Q. Mr. Rafalski never worked in
19 DEA headquarters, correct?

20 A. I honestly don't know his
21 complete background. So I can't --
22 without reviewing his background once
23 more, I can't tell you one way or the
24 other because I can't remember it in all

1 that detail.

2 Q. What was Mr. Rafalski's job
3 title?

4 A. As I said to you, I don't
5 remember it off the top of my head. So
6 if there's a document you'd like me to
7 look at, I'll be happy to.

8 Q. Sir, does it help refresh
9 your recollection that Mr. Rafalski was a
10 diversion investigator in the Detroit
11 field office?

12 A. Again, I'd like to see
13 whatever document you're referring to,
14 Counsel, because if --

15 Q. If Mr. Rafalski never worked
16 at DEA headquarters, could Mallinckrodt
17 have relied on his understanding of the
18 Controlled Substances Act?

19 MR. BOGLE: Object to form.

20 THE WITNESS: Again, I'd
21 like to know what you mean by
22 "rely."

23 BY MR. DAVISON:

24 Q. Well, I asked you earlier

1 with respect to Exhibit 22, whether this
2 was an example of DEA telling
3 Mallinckrodt that there's no regulatory
4 requirement to know the customer's
5 customer.

6 And I'm paraphrasing. But
7 one of the statements that you made was
8 that no, because the policy from DEA
9 comes from corporate headquarters.

10 So I -- question, was your
11 concern that that information was coming
12 from a field office?

13 MR. BOGLE: Object to form.

14 THE WITNESS: Well, first
15 off, my concern with the document
16 that you had showed me was it is a
17 Mallinckrodt employee's
18 recollection of a conversation
19 rather than -- rather than any --
20 of how that conversation
21 transpired, there's no way to say
22 whether or not that's an accurate
23 version of the conversation or
24 not.

1 So I honestly don't know
2 what DI Heather White actually
3 said, except for the way it's
4 represented on the document.
5 That's my first concern.

6 My second concern would be,
7 again, if you get something, you
8 know, regulatory professionals and
9 compliance professionals know
10 that, again, if you get -- if you
11 hear something from a field office
12 that doesn't comport with what
13 you've heard before, you need to
14 go to the source that makes
15 policy, in this case we are
16 talking DEA headquarters, and
17 inquire further.

18 Hey, am I hearing what's
19 right? Is this the right
20 statement of the policy? Et
21 cetera. Because, again, employees
22 in the field -- and Mallinckrodt
23 has the same experience with sales
24 reps -- sometimes do not state

1 policy correctly.

2 BY MR. DAVISON:

3 Q. Fair enough, sir.

4 So if there is -- strike
5 that.

6 If the interpretation of the
7 requirements of the Controlled Substances
8 Act for manufacturers differ between
9 Mr. Rafalski, who is at a field office,
10 and members of DEA who are at
11 headquarters, you would say that you
12 listen to the members of DEA that are at
13 headquarters, correct?

14 MR. BOGLE: Object to form.
15 Misstates his testimony.

16 THE WITNESS: Again, I would
17 say you would -- you would inquire
18 from headquarters, this is what
19 I've heard, is this accurate, and
20 get a read from headquarters of
21 whether or not what you're hearing
22 is accurate or not.

23 BY MR. DAVISON:

24 Q. And headquarters' view is

1 what determines there, correct?

2 A. Headquarters sets policies
3 that if you want to know what the DEA's
4 policy is on a particular topic, you need
5 to hear it from headquarters.

6 Q. Thank you, sir.

7 I'd like to -- so we were
8 talking about chargeback data. And we --
9 we went a little afield. But turning
10 back to chargeback data, sir.

11 In your report do you
12 suggest any metric or method to use in
13 analyzing chargeback data?

14 A. I don't suggest utilizing a
15 specific methodology for analyzing it.
16 What I'm saying is it's a set of data
17 that you -- that a manufacturer should
18 incorporate into their suspicious order
19 monitoring program as appropriate.

20 For example, as you and I
21 just discussed, not everything has a
22 chargeback, so obviously for certain
23 transactions you can't use data that
24 doesn't exist.

1 What I'm saying is it's up
2 to the manufacturer to incorporate it and
3 they should make an effort to use that
4 data.

5 Q. And, sir, with respect to
6 using that data, it could be used
7 differently by different manufacturers,
8 correct?

9 MR. BOGLE: Object to form.

10 THE WITNESS: Could you --
11 could you restate the question for
12 me, please?

13 BY MR. DAVISON:

14 Q. Sure.

15 Under the -- the
16 Dr. Whitelaw good manufacturers
17 controlled substances compliance
18 program -- or excuse me, anti-diversion
19 compliance program --

20 A. You mean under the
21 attributes that I list in my report that
22 I gleaned from experience in the federal
23 sentencing guidelines and Controlled
24 Substances Act, et cetera? Is that what

1 we're referring to?

2 Q. The attributes that are
3 listed in your report on Page 36.

4 A. Okay. Great.

5 Q. You don't define a way that
6 you expect manufacturers to monitor
7 chargebacks, correct?

8 A. No, I do not define a
9 specific way for...

10 Q. Are you aware of DEA ever
11 suggesting a specific metric or method
12 that manufacturers are to use in
13 analyzing chargeback data?

14 MR. BOGLE: Object to form.

15 THE WITNESS: No, I am not
16 aware of DEA ever suggesting a
17 specific methodology to analyze
18 and review chargeback data.

19 BY MR. DAVISON:

20 Q. So under the expectations
21 that you have for a manufacturer's
22 program, is one way the manufacturer
23 could utilize chargeback data to utilize
24 the data to look at its distributors and

1 where the product is going, and inform
2 DEA of that information regarding its
3 distributor customers?

4 MR. BOGLE: Object to form.

5 THE WITNESS: Well, that's
6 certainly part of the equation.
7 You're missing the last part of
8 the equation, which would be, if
9 you think you need to inform DEA
10 and your product is going in the
11 wrong -- going in the wrong
12 direction because of chargeback
13 data, you should be taking steps
14 to make sure that that product
15 doesn't -- that product pipeline
16 doesn't continue to flow.

17 BY MR. DAVISON:

18 Q. And would one way of doing
19 that be to restrict chargebacks so
20 that -- for certain pharmacies that you
21 may have questions about?

22 MR. BOGLE: Object to form.

23 THE WITNESS: Again, it's a
24 partial -- partial answer. But

1 again, you want to talk about the
2 bigger picture? That is one part
3 of it. But, again, you should
4 also then be looking at your
5 distributors and asking them some
6 serious questions as to, all
7 right, if I'm seeing this behavior
8 from this pharmacy, and it looks
9 to be an outlier, and I am
10 concerned about it, could you
11 please tell me what you're doing
12 about it, because you're my
13 distributor.

14 BY MR. DAVISON:

15 Q. Fair enough.

16 So one thing you could do is
17 you could restrict the chargebacks, then
18 conduct an audit of the distributor,
19 correct?

20 A. Yes. And at the same time
21 request that the distributor stop filling
22 orders for that particular pharmacy that
23 you are concerned about with your
24 product, so that again you're not making

1 the problem worse.

2 Q. Fair enough.

3 Now, sir, I'd like -- we can
4 turn back to 36 just so we're on the same
5 page.

6 A. Sure.

7 Q. All right. So Number 2
8 here, we have individual retail pharmacy
9 activity. And I think we've discussed
10 maybe a little bit about this already
11 with respect to chargebacks.

12 But -- but my question was,
13 you write, "Like the distributor
14 thresholds outlined above, the
15 manufacturer establishes ordering levels
16 for specific pharmacies which if exceeded
17 trigger the manufacturer to be concerned
18 that the orders are suspicious and that
19 action is needed."

20 What does that mean, sir?

21 A. I'm not sure where you're --
22 what it means is for each pharmacy you're
23 selling to, you are tracking your product
24 going to, you should establish thresholds

1 or some sort of flag of when the ordering
2 pattern, volume, frequency, becomes of
3 concern, that leads you to want to do
4 further inquiry and find out what's going
5 on.

6 Q. All right. So I just want
7 to make sure I understand. You said for
8 each pharmacy you're selling to. Who is
9 the "your" there?

10 A. The manufacturer.

11 Q. Okay. So if the
12 manufacturer is not selling to individual
13 retail pharmacies --

14 A. Through the -- no, I'm
15 talking about --

16 MR. BOGLE: Wait, wait.
17 Wait until --

18 THE WITNESS: Sorry.

19 MR. BOGLE: Wait until he
20 finishes his question.

21 BY MR. DAVISON:

22 Q. So if the manufacturer is
23 not selling to individual retail
24 pharmacies, then this would not apply,

1 correct?

2 MR. BOGLE: Object to form.

3 THE WITNESS: I think you're
4 misunderstand -- I probably wasn't
5 clear. What I'm saying is
6 wherever your product is ending up
7 in pharmacy hands, you should have
8 thresholds, especially for this
9 type of product -- we're talking
10 about opioids -- and be looking at
11 their patterns.

12 BY MR. DAVISON:

13 Q. So just so I follow this,
14 even though a manufacturer is not selling
15 to any of these pharmacies, they should
16 set a threshold level of pills purchased
17 from all distributors?

18 MR. BOGLE: Object to form.

19 THE WITNESS: What I'm
20 saying is you should have a
21 threshold of what -- of your
22 product going into that pharmacy,
23 and what you start to get
24 uncomfortable at. That's what I'm

1 trying -- that's what I'm trying
2 to say.

3 BY MR. DAVISON:

4 Q. And how would you track
5 that?

6 A. I'm sorry? Probably
7 starting with chargeback data, but there
8 might be other ways. Again, I wasn't
9 trying to give you an exhaustive list.

10 Q. All right. And so for every
11 pharmacy that buys from any distributor,
12 Mallinckrodt should set a threshold
13 across all distributors, and if it goes
14 above that threshold, then would report
15 it to DEA?

16 A. I didn't say report it to
17 DEA.

18 MR. BOGLE: Object to form.

19 THE WITNESS: I said
20 investigate it further. That
21 could be contacting your
22 wholesaler and asking what's going
23 on. You could be conducting your
24 own investigation, your own audit

1 of the wholesaler. But again, you
2 should be asking the question why.
3 You need to have something that
4 triggers the question why and you
5 should be asking the question, why
6 is this happening, why am I seeing
7 what I'm seeing, and is it a
8 problem or isn't it.

9 BY MR. DAVISON:

10 Q. Sir, you're aware that
11 manufacturers receive chargebacks after
12 the sales have been made, correct?

13 A. Yes. I'm aware of that
14 fact.

15 Q. You write in, in
16 subsection --

17 A. But it doesn't any --

18 Q. Excuse me, sir. You write
19 in Subsection A --

20 MR. BOGLE: Were you done?

21 BY MR. DAVISON:

22 Q. -- "Where appropriate,
23 information" --

24 A. No, I wasn't.

1 Q. -- "obtained through the
2 manufacturer's sample accountability
3 program is factored into the controlled
4 substance monitoring program."

5 Did I read that correctly?

6 MR. BOGLE: Why don't you
7 let him finish his last answer
8 before you ask that question.

9 MR. DAVISON: No. Special
10 Master Cohen had very clear on an
11 order on this. If you're going to
12 continue to flout it, we can call
13 him on it. But it's my
14 deposition. It's not a trial
15 deposition. It's a discovery
16 deposition. And if he's going to
17 say things that are not responsive
18 to the question --

19 MR. BOGLE: I think he
20 was -- we didn't know what he was
21 going to say. You stopped him
22 from saying anything.

23 Listen, if you want to go
24 on, then let me make a note that

1 you are not letting the witness
2 finish his answer.

3 BY MR. DAVISON:

4 Q. Sir, go ahead and finish,
5 and we'll make a note of an inappropriate
6 objection from your counsel.

7 THE WITNESS: That's fine.
8 Can you read back where we were
9 because I've lost track.

10 (Whereupon, the court
11 reporter read back the requested
12 portion of testimony.)

13 THE WITNESS: I am aware
14 that chargeback data are received
15 after -- received retrospectively,
16 which is what your question was,
17 but it doesn't make using it or
18 not using it any less valid.

19 You are talking about a
20 timing issue here. I'm not saying
21 just because it's not realtime
22 data, which is what you are
23 describing, doesn't make its use
24 or rejection of use any less --

1 it's not less valid just because
2 it's retrospective data. It's
3 still data.

4 MR. DAVISON: Moving -- move
5 to strike everything after "I am
6 aware that chargeback data are
7 received retrospectively, which is
8 what your question was."

9 BY MR. DAVISON:

10 Q. All right. I'd like to turn
11 to Subsection A of Number 2.

12 You write, "Where
13 appropriate information obtained through
14 the manufacturer's sample accountability,
15 e.g., PDMA program, is factored into the
16 controlled substances monitoring
17 program."

18 Sir, did Mallinckrodt
19 provide samples of the controlled
20 substances at issue in this case?

21 A. To my knowledge, no, they
22 did not.

23 Q. All right. And you are only
24 stating that this would be where

1 appropriate, correct?

2 A. That was why it was stated
3 as where appropriate.

4 Q. And so for Mallinckrodt, and
5 with respect to the opioids at issue in
6 this case, it would not be something that
7 would be utilized in a controlled
8 substances --

9 A. I was talking from a bigger
10 picture. If you are dropping
11 noncontrolled samples, obviously you're
12 not dropping controlled samples. You
13 have data that comes out of that system,
14 you should make use of it if it's
15 relevant, if it overlaps a particular
16 prescriber for example, overlaps a
17 particular pharmacy.

18 Again, the whole
19 conversation we're having around is know
20 your customer's customer. And,
21 therefore, using any and all data
22 available to you that you have available
23 to you, to create as fair and accurate a
24 profile of your customer's customer as

1 you can.

2 Q. Sir, have you ever seen
3 written documentation from the Drug
4 Enforcement Agency that state a
5 manufacturer has an obligation to know
6 its customer customer -- customer's
7 customer?

8 MR. BOGLE: Object to form.

9 THE WITNESS: I'm sorry.

10 Can you state that again.

11 BY MR. DAVISON:

12 Q. Yeah. Have you ever seen
13 written documentation from the Drug
14 Enforcement Agency that requires a
15 manufacturer to know its customer's
16 customer?

17 MR. BOGLE: Object to form.

18 THE WITNESS: I have to go
19 back and review my entire report
20 from beginning find -- to look to
21 answer your question completely.
22 We can do that if you'd like.

23 BY MR. DAVISON:

24 Q. So sitting here today

1 without reviewing your report, you can't
2 answer that question. Is that fair?

3 MR. BOGLE: Object to form.
4 Misstates his testimony.

5 THE WITNESS: What I said
6 was I'd have to review it to be
7 able to find the specific document
8 that you're looking for. I don't
9 recall a specific document off the
10 top of my head.

11 BY MR. DAVISON:

12 Q. Well, do you recall
13 generally that DEA guidance exists that a
14 manufacturer is required to review its
15 customer's customer?

16 A. Again, I would want to
17 review my report.

18 Q. So you don't have a
19 recollection of that sitting here today?

20 A. I can't recall off the top
21 of my head.

22 Q. Thank you, sir.

23 MR. BOGLE: When you reach a
24 good stopping point, we're a

1 little over an hour. Take a quick
2 break.

3 MR. DAVISON: Yeah, right
4 now is actually a good breaking
5 place.

6 THE VIDEOGRAPHER: Going off
7 the record at 3:30 p.m.

8 (Short break.)

9 THE VIDEOGRAPHER: Back on
10 the record at 3:45 p.m.

11 BY MR. DAVISON:

12 Q. All right. Dr. Whitelaw,
13 I'm on Page 36 and 37 of your report.

14 A. I'm still here, yes.

15 Q. Great. So I'm on actually,
16 37, I should say, so you don't have to
17 turn the page.

18 A. Okay.

19 Q. So we talked a little bit
20 about actions that a manufacturer could
21 take if they have questions about a
22 pharmacy that is purchasing their product
23 from a distributor, correct?

24 A. That is correct. We did

1 have that conversation.

2 Q. And would those be the
3 actions that you'd expect -- so you'd
4 expect certain actions under Number 3 of
5 your expectations labeled "Taking
6 Action"? Is that what you're referring
7 to?

8 A. Yeah, that's what I'm
9 referring to. Yes.

10 Q. You -- excuse me.
11 You write, "The manufacturer
12 notifies and provides details of the
13 suspicious activity to both the DEA and
14 the distributor," correct?

15 A. That's what I'm suggesting,
16 yes.

17 Q. So that could be in a
18 letter -- letter that the manufacturer
19 sends to a distributor, the DEA at the
20 same time, saying we have some concerns
21 about this pharmacy, correct?

22 A. I would say that would be --
23 certainly be one method of doing it, yes.

24 Q. All right. "The

1 manufacturer demands the distributor, and
2 any secondary distributor if known,
3 follow up and take appropriate action
4 regarding the highlighted pharmacies."

5 That's letter B of your
6 "Taking Action," correct?

7 A. That is correct.

8 Q. And one way of doing that
9 would be to request the due diligence
10 files from the distributor so the
11 manufacturer can look at what the
12 distributor knows about the pharmacy,
13 correct?

14 A. That's one method. Not the
15 only method. But certainly an -- a
16 method.

17 Q. And, "The manufacturer
18 maintains contact with the distributor
19 and any secondary distributor if known,
20 requiring them to provide details on the
21 outcome of any investigations including
22 actions taken by the distributors against
23 the pharmacies."

24 And this could be included

1 through an audit or a follow-up
2 conversation with the distributor,
3 correct?

4 A. Either, you could do either.
5 My suggestion would be that you would
6 probably want to have follow-up
7 conversation with the distributor.
8 Because if you're doing an audit on a
9 annual basis, which it tends to be
10 usually an annual audit cycle, a year is
11 an awful long time to wait to follow up
12 to make sure that this hasn't fallen into
13 the black hole.

14 So that's really what we are
15 talking about here, is you provide the
16 information to the distributor and the
17 distributor doesn't do anything to it.
18 And nobody bothers to follow up till a
19 year or more has passed. So that was
20 the...

21 Q. Looking at Number 4 of your
22 expectations, lists audits. "The
23 manufacturer conducts both routine and
24 for-cause audits of these distributors

1 anti-diversion programs," correct?

2 A. Yes.

3 Q. Are you aware that
4 Mallinckrodt conducted audits of its
5 distributor customers?

6 MR. BOGLE: Objection as to
7 time. Form as to time.

8 THE WITNESS: Can you be
9 more specific for me, please?

10 BY MR. DAVISON:

11 Q. Well, my question is -- is
12 general now. So all the time of your
13 review period, which I think was 1996 to
14 2018.

15 A. I'd have to go back and look
16 at my report to be absolutely certain.
17 So give me a minute.

18 Q. So I just want to -- the
19 question is yes or no. Are you aware
20 whether Mallinckrodt did audits of
21 distributors during your review period?

22 MR. BOGLE: Object to form.

23 THE WITNESS: And again,

24 I -- to be precise in my answer to

1 you, I would need to consult my
2 report. So if you're going to let
3 me consult my report, I can give
4 you an answer. Otherwise...

5 BY MR. DAVISON:

6 Q. Sir, do you plan to bring
7 your report with you to trial?

8 A. I would plan to have it
9 available, if needed. Why?

10 Q. So do you plan to review it
11 when you're on the jury stand?

12 A. I honestly hadn't thought
13 that far ahead if you want to -- to be
14 honest.

15 Q. So you may sit there in
16 front of a jury with your report in front
17 of you, to look back on as you're
18 answering questions from plaintiffs
19 during the trial?

20 MR. BOGLE: Object to form.

21 THE WITNESS: Again, we're
22 here -- we're here at a
23 deposition. We haven't gotten to
24 that level of discussion. So I'm

1 going to say to you, I don't know.

2 BY MR. DAVISON:

3 Q. Sir, out of the -- let me
4 ask a question because I've forgotten the
5 number.

6 How many hours have you
7 spent on your report in preparation for
8 this case?

9 A. Around 1200.

10 Q. Okay. That's what I
11 thought, but I wasn't certain so I didn't
12 want to get it wrong.

13 How many of those 1200 hours
14 were spent in your review of
15 Mallinckrodt?

16 A. I would have to go look at
17 precisely. But it -- for each one,
18 each -- in general, each company I looked
19 at took about a month's worth of work.

20 Q. So you spent about a month's
21 worth of work on Mallinckrodt and you
22 can't recall without going back into your
23 report whether Mallinckrodt ever
24 conducted an audit of one of its

1 distributor customers?

2 MR. BOGLE: Object to form.

3 THE WITNESS: What I'm

4 saying, sir, is I would want to

5 consult my reports so that I give

6 you an accurate answer. That's

7 what I've been saying to you all

8 along.

9 BY MR. DAVISON:

10 Q. All right. So the answer is

11 you can't tell me the answer without

12 looking at your report?

13 MR. BOGLE: Object to form.

14 THE WITNESS: Did he say

15 anything?

16 MR. BOGLE: You can answer.

17 THE WITNESS: I'm not sure

18 there was a question, but...

19 BY MR. DAVISON:

20 Q. So the answer is that you

21 cannot tell me yes or no whether

22 Mallinckrodt has done an audit of a

23 distributor customer without reviewing

24 your report?

1 MR. BOGLE: Object to form.

2 THE WITNESS: What -- what
3 I'm telling you is I would like to
4 review my report before I answer
5 your question.

6 BY MR. DAVISON:

7 Q. So, sir, that's not an
8 answer to my question.

9 My question is yes or no,
10 can you tell me?

11 MR. BOGLE: Object to form.

12 THE WITNESS: I can't recall
13 off the top of my head without
14 reviewing my report.

15 BY MR. DAVISON:

16 Q. That's exactly the answer
17 that I was asking a question about, sir,
18 thank you.

19 All right. Sir, if you can
20 turn to Page 42 of your report.

21 A. Yes.

22 Q. In Section 6.7, it says,
23 "Manufacturer - Prescriber Relationship,"
24 right?

1 A. It does.

2 Q. And you state that "a
3 manufacturer should instruct and require
4 its sales representatives and inhouse
5 field support and marketing personnel to
6 provide any observations of potential
7 diversionary behavior to their inhouse
8 compliance department for further
9 evaluation and potential action,"
10 correct?

11 A. That is correct.

12 Q. And, sir, is -- is this
13 something that's explicitly laid out in
14 the CSA?

15 A. It is embedded in the CSA.

16 Q. And it's embedded under
17 those -- those four words of controls
18 against effective diversion, correct?

19 MR. BOGLE: Object to form.

20 THE WITNESS: Yes, as well
21 as under the federal sentencing
22 guidelines of what an effective
23 compliance program looks like as
24 well, so...

1 MR. DAVISON: Move to strike
2 as nonresponsive "as well as under
3 the federal sentencing guidelines
4 of what an effective compliance
5 program looks like as well."

6 BY MR. DAVISON:

7 Q. And, sir, there's nothing in
8 the suspicious order monitoring
9 regulation that requires sales reps to be
10 involved in monitoring physicians,
11 correct?

12 MR. BOGLE: Object to form.

13 THE WITNESS: Could you
14 state the question again for me,
15 please?

16 BY MR. DAVISON:

17 Q. There's nothing in the
18 suspicious order monitoring regulation
19 that requires sales reps to be involved
20 in monitoring physician behavior,
21 correct?

22 MR. BOGLE: Object to form.

23 THE WITNESS: There is no
24 specific wording in the

1 regulation.

2 BY MR. DAVISON:

3 Q. Thank you.

4 Sir, you understand the
5 differences between generic
6 pharmaceutical products and branded
7 pharmaceutical products?

8 A. I do.

9 Q. All right. And you
10 understand that generics products are --
11 are not promoted by a field sales force
12 that interacts with physicians, correct?

13 A. In general, no, they are
14 not.

15 Q. Okay. And, sir,
16 Mallinckrodt did not promote its generic
17 products with a field sales force that
18 interacted directly with the physicians,
19 correct?

20 A. I did not see anything to
21 that effect.

22 Q. And so you're not claiming
23 that there is an obligation of a generic
24 manufacturer to somehow promote its --

1 excuse me -- strike that.

2 You're not claiming that a
3 generic manufacturer has an obligation to
4 monitor physicians through a sales force,
5 correct?

6 MR. BOGLE: Object to form.

7 THE WITNESS: I think you're
8 missing the whole point of this
9 section, which is basically, if
10 you have a sales force and the
11 sales force calls on the
12 physician, and they observe bad
13 behavior, troubling behavior is
14 perhaps a better term, that
15 information should be taken back
16 to headquarters and reported to
17 the compliance department. You
18 just don't ignore it and pretend
19 it's not happening. That's what
20 I'm talking about.

21 BY MR. DAVISON:

22 Q. And so within that statement
23 is, if you don't have a sales force, you
24 don't have an obligation to create one to

1 somehow monitor physicians, correct?

2 A. I'm not saying that you have
3 to create a sales force. I'm saying
4 again the whole gist of this is you have
5 available information, if you have boots
6 on the ground, if you have people out
7 there who are observing behavior and they
8 see something that's troubling, you know,
9 it's about as basic as what you see on
10 Amtrak these days. If you see something,
11 say something.

12 Q. And all of that -- that
13 obligation, again, comes from the four
14 words "effective controls against
15 diversion," right?

16 A. It comes from the federal
17 sentencing guidelines together with the
18 four words of "effective controls against
19 diversion," yes.

20 Q. You also mention IMS data,
21 correct?

22 A. Is there a particular
23 section that you're looking at?

24 Q. Yeah. Page 43. At the top.

1 "Upon receipt of this information, the
2 compliance department or other
3 experienced investigators should conduct
4 an appropriate investigation to determine
5 the validity of the information using all
6 available sources of information, e.g.,
7 the internet, IMS data, et cetera."

8 A. Yes. I see what I said.

9 Q. All right. You're aware
10 that not all manufacturers purchase IMS
11 data, correct?

12 A. I am aware of that fact.

13 Q. And you're not stating that
14 there's a requirement under the CSA for a
15 manufacturer to purchase IMS data, right?

16 MR. BOGLE: Object to form.

17 THE WITNESS: Again, I think
18 we're missing the point of what
19 I'm conveying. If IMS data is
20 available, it should be used.

21 If you have data inhouse
22 that you have access to that's
23 pertinent to keeping, you know, to
24 keeping an eye out for suspicious

1 behavior, you should be using that
2 data.

3 BY MR. DAVISON:

4 Q. And sir, I understand that,
5 I just want to be clear, I don't think
6 I'm missing the point. I'm asking you
7 specific questions about whether or not
8 things have to use it. The reason I'm
9 doing that is because we need to have an
10 understanding of what your opinions are.

11 So I understand what you
12 said, but if you could answer my
13 question.

14 A manufacturer is not
15 required by the CSA to purchase IMS data,
16 correct?

17 MR. BOGLE: Object to form.

18 THE WITNESS: The words
19 "purchase IMS data" are not in the
20 CSA requirements, no.

21 BY MR. DAVISON:

22 Q. And even under your opinion,
23 you're not saying that they are required
24 to do that, whether the words are in the

1 CSA or not?

2 MR. BOGLE: Object to form.

3 THE WITNESS: What I'm

4 saying, obviously, if the words

5 were in the CSA that would be a

6 different story, but since they

7 are not, what we're talking

8 about -- no, I'm not saying that

9 you have to go out and buy it.

10 I'm saying if you have it inhouse,

11 you ought to be using it.

12 MR. DAVISON: Can we go off

13 the record for just a second. My

14 battery is almost dead on this.

15 THE VIDEOGRAPHER: Going off

16 the record 3:57 p.m.

17 (Brief pause.)

18 THE VIDEOGRAPHER: Back on

19 the record at 3:57 p.m.

20 BY MR. DAVISON:

21 Q. All right, sir. We've

22 talked about the general expectations.

23 I'd now like to turn to your review

24 specifically of Mallinckrodt. And just

1 to help you out with that. It starts on
2 Page 208. But I wanted to start by
3 asking about your evaluation. If you can
4 turn to Page 43. Sorry.

5 A. Okay.

6 Q. All right. So at the bottom
7 of the page, you write, "For each company
8 the analysis focuses on answering two
9 questions. The first question is whether
10 objective evidence exists supporting that
11 the company being reviewed worked to
12 establish a suspicious order monitoring
13 system as well as controlled substances
14 and corporate compliance programs."

15 Did I review that correctly?
16 Excuse me. Did I read that correctly?

17 A. Yes.

18 Q. Sir, did you find objective
19 evidence that Mallinckrodt worked to
20 establish a suspicious order monitoring
21 system as well as controlled substances
22 and corporate compliance programs?

23 MR. BOGLE: Object to form.

24 THE WITNESS: Yes, I did.

1 BY MR. DAVISON:

2 Q. Thank you. And so the
3 second question is, "Whether there is
4 objective evidence showing that the
5 company met its three-prong program
6 effectiveness requirement by: A, having
7 a program that prevents and detects
8 criminal conduct by an organization's
9 employees; and B, maintaining effective
10 controls against diversion; including, C,
11 maintaining and operating an effective
12 system to identify, hold, investigate,
13 and report suspicious orders of
14 controlled substances."

15 Did I read that correctly?

16 A. Yes.

17 Q. So with respect to the
18 Mallinckrodt section of your report, was
19 your focus on answering that second
20 question?

21 MR. BOGLE: Object to form.
22 Overbroad.

23 THE WITNESS: Well, my focus
24 was answering both questions, but

1 we obviously had enough evidence
2 that I reviewed to get past the
3 first level. So yes, it was on
4 the second -- the details are on
5 the second part, yes.

6 BY MR. DAVISON:

7 Q. Thank you. You can turn to
8 Page 208.

9 Sir, in your evaluation of
10 Mallinckrodt's suspicious order
11 monitoring -- excuse me. Strike that.

12 In your evaluation of
13 Mallinckrodt's anti-diversion compliance
14 program, you used the same methodology
15 that we discussed earlier, correct?

16 A. Yes, sir.

17 Q. So you reviewed the standard
18 operating procedures?

19 A. I reviewed a whole host of
20 information I asked for. I applied my
21 expertise and experience, looked at those
22 documents, conversations. It's the
23 same -- it's the same methodology that I
24 applied to every other company reviewed

1 in this report.

2 Q. And that's because
3 compliance programs have to be looked at
4 in the totality, correct?

5 A. I believe so, yes.

6 Q. And I believe you testified
7 earlier that you had requested certain
8 categories of documents from plaintiffs
9 and that those categories were based on
10 the seven, now eight federal sentencing
11 guidelines; is that correct?

12 A. Yes. That's the framework I
13 was using, yes.

14 Q. And -- and you also stated
15 that you requested transcripts from the
16 plaintiffs' attorneys, correct?

17 A. You mean deposition
18 transcripts?

19 Q. Absolutely. Deposition
20 transcripts.

21 A. Yes, I requested deposition
22 transcripts.

23 Q. Okay. And when you
24 requested transcripts, did you request

1 categories of transcripts?

2 MR. BOGLE: Object to form.

3 THE WITNESS: I requested
4 people's transcripts. I'm not
5 sure -- I'm not sure I'm following
6 you yet.

7 BY MR. DAVISON:

8 Q. Well, how did you determine
9 which people to request a transcript for?

10 A. I utilized the
11 organizational charts that I had seen,
12 had -- had conversations with counsel,
13 who were -- who was likely to have the
14 most responsive information based on the
15 depositions that have been taken in the
16 categories I was looking in. It was a
17 whole series of -- it was an iterative
18 process.

19 Q. All right. And so you
20 stated that you utilized the
21 organizational charts --

22 A. When I had them.

23 Q. Excuse me. The part -- you
24 utilized them as one of other ways of --

1 of reviewing them, correct?

2 A. Yes.

3 Q. And did you request
4 transcripts for example, for each
5 employee that was a member of a certain
6 category?

7 A. I'm not sure I'm
8 following -- you've lost me.

9 Q. Fair enough.
10 Sir, you reviewed
11 transcripts of Mallinckrodt's national
12 account managers; is that correct?

13 A. Yes. I reviewed
14 transcripts.

15 Q. Did you request from
16 plaintiffs' counsel that they provide you
17 transcripts of every national account
18 manager for which a deposition was taken?

19 A. I honestly don't recall
20 whether I asked for all or some. I can't
21 tell you at this point.

22 Q. Would it be your standard
23 practice to -- to interview every
24 employee within a certain title?

1 MR. BOGLE: Object to form.

2 MR. DAVISON: Strike that,

3 that was a bad question.

4 BY MR. DAVISON:

5 Q. Under your methodology that
6 we had discussed earlier --

7 A. Yes.

8 Q. -- would your expectation be
9 that you would interview multiple
10 employees with the same position?

11 MR. BOGLE: Object to form.

12 THE WITNESS: Again,
13 within -- I would interview those
14 employees I needed or felt were
15 necessary to form my opinion.

16 I don't have a set number.
17 If you're looking for a set
18 number, I don't have that. I
19 don't -- I don't use a set number.

20 BY MR. DAVISON:

21 Q. And you don't recall, with
22 respect to Mallinckrodt, whether you
23 requested from plaintiffs all of the
24 deposition transcripts of national

1 account managers or only a couple?

2 A. I honestly do not recall.

3 Q. Do you remember whether you
4 asked for testimony of national account
5 managers at all?

6 A. I did ask for depositions
7 from national account managers.

8 Q. And did you request specific
9 people?

10 A. As I said, I don't recall
11 this precise request. I do know I
12 requested national account manager
13 depositions.

14 Q. Did you request deposition
15 transcripts of sales reps?

16 A. I don't recall a specific
17 request for those.

18 Q. Did you request deposition
19 transcripts for Mallinckrodt's head of
20 sales?

21 A. Again, I don't recall a
22 specific request for that deposition.

23 Q. Sir, did you request the
24 deposition transcript of Mallinckrodt's

1 manager of controlled substance
2 compliance?

3 A. Can you be more specific on
4 period of time, because again I know
5 people's titles change. Yes, I would
6 have requested the key controlled
7 substances personnel. So can you -- I
8 need you to be more specific.

9 Q. Sure. Did you request
10 deposition transcripts from
11 Mallinckrodt's current manager of
12 controlled substance compliance?

13 MR. BOGLE: Object to form.

14 THE WITNESS: Again, I would
15 have asked for transcripts from
16 the key people responsible for
17 controlled substance compliance
18 review. And again, if you're
19 asking me about a specific name --

20 BY MR. DAVISON:

21 Q. Well, based on a -- on a job
22 title, sir, would a manager of controlled
23 substance compliance be someone that
24 would be important to review in

1 evaluating a manufacturer's controlled
2 substance compliance program?

3 MR. BOGLE: Object to form.

4 THE WITNESS: There is a
5 potential, but there's also the
6 potential that you are looking for
7 the if. You're saying -- are they
8 the head of the programs? Are
9 they the ones ultimately
10 responsible? Are they the highest
11 authority responsible? Do they
12 have day-to-day operational
13 oversight?

14 There are a number of
15 factors in selecting whether or
16 not you talk to certain people.

17 BY MR. DAVISON:

18 Q. Well, sir, you -- you would
19 agree with me that to do an effective
20 internal investigation, you can't just
21 talk to the highest people up there,
22 right?

23 MR. BOGLE: Object to form.

24 THE WITNESS: I think it

1 depends on the kind of
2 investigation you're doing and
3 what you're investigating.

4 BY MR. DAVISON:

5 Q. Well, with -- with your
6 investigation for this litigation of
7 Mallinckrodt, would it have been
8 sufficient for you to just talk to the
9 highest people at Mallinckrodt?

10 MR. BOGLE: Object to form.

11 THE WITNESS: Well, you're
12 making it sound like all I did was
13 look at -- again, if that was all
14 you did was -- was depositions in
15 a -- in a vacuum, no, it would not
16 be.

17 But again there's a whole
18 lot of other documents and
19 information that went into this
20 review.

21 BY MR. DAVISON:

22 Q. Sir, did you request from
23 plaintiffs that they provide you with
24 testimony -- excuse me -- deposition

1 transcripts of any testimony taken for
2 people in Mallinckrodt's controlled
3 substance compliance department?

4 MR. BOGLE: Object to form.

5 THE WITNESS: To the best of
6 my recollection, I did.

7 BY MR. DAVISON:

8 Q. Sir, do you know who Eileen
9 Spalding is?

10 A. I know the name.

11 Q. I'll represent to you that
12 she is Mallinckrodt's current manager of
13 controlled substance compliance. Do you
14 recall reviewing her testimony?

15 A. I honestly don't recall her
16 deposition. But I can go -- again, let's
17 look at the reliance list. It will tell
18 you whose depositions --

19 Q. No problem, sir, that's on
20 Page 2 -- 277.

21 A. I do not see her deposition.

22 Q. Plaintiffs didn't give you
23 Eileen Spalding's deposition transcript,
24 correct?

1 A. What I said was, I don't
2 recall reviewing Eileen Spalding's
3 deposition transcript.

4 Q. Well, if you had reviewed
5 it, it would be right here in -- in your
6 report, right, sir?

7 A. Unless it was mistakenly
8 left off, yes, it should be there.

9 Q. All right. And did you
10 review all the transcripts that
11 plaintiffs provided you?

12 A. Again, I don't remember all
13 the transcripts that I have. I've seen
14 so many transcripts. So I -- I can't
15 answer that question.

16 Q. I think my question is a
17 little bit different. I'm not asking if
18 you remember all -- all the transcripts
19 you have.

20 I'm asking if you reviewed
21 all the transcripts that plaintiffs
22 provided you.

23 A. Well, since the only
24 transcripts I reviewed would have come

1 from my requests of plaintiffs' counsel,
2 again I don't -- don't know all of the
3 list I have. But again, everything
4 that's on my list here, I did review.

5 Q. And was it your practice in
6 the -- the 1200 hours that you spent, to
7 review all of the transcripts that
8 plaintiffs' counsel provided you?

9 A. Again, if I had it, I would
10 have looked at it.

11 Q. Thank you, sir.

12 Sir, are you offering an
13 opinion as to the effectiveness of
14 Mallinckrodt's current controlled
15 substances compliance program?

16 A. I am offering an opinion
17 based on Mallinckrodt's controlled
18 substances compliance program for the
19 period that's in my report.

20 Q. All right. So not one for
21 today, correct?

22 MR. BOGLE: Object to form.

23 THE WITNESS: I'm sorry?

24 BY MR. DAVISON:

1 Q. You are not offering an
2 opinion as to Mallinckrodt's current
3 controlled substances compliance program?

4 A. I'm offering it for the time
5 frame that's set out in my report.

6 Q. And the time frame set out
7 in your report is 1996 to 2018; is that
8 correct?

9 A. That is correct.

10 Q. So you're offering an
11 opinion on Mallinckrodt's controlled
12 substances compliance program in 2018,
13 correct?

14 A. Correct.

15 Q. 2017?

16 A. Yes.

17 Q. We can go all the way back
18 to 1996?

19 A. We can.

20 Q. So you're offering an
21 opinion for every single year of
22 Mallinckrodt's controlled substance
23 compliance program 1996 to 2018?

24 A. I am offering an opinion

1 about the effectiveness of the program
2 for that period of time.

3 Q. Sir, sitting here today, can
4 you think of a single document that you
5 reviewed regarding Mallinckrodt's
6 controlled substance compliance program
7 that was later than 2012?

8 A. Again, I don't recall. I'd
9 have to go look at all the documents and
10 all the dates, sir.

11 Q. Fair enough.

12 (Document marked for
13 identification as Exhibit
14 Whitelaw-23.)

15 BY MR. DAVISON:

16 Q. I'm going to mark
17 Exhibit 23, which is a chart that may
18 help us a little bit. We put this
19 together. This isn't anything that
20 Mallinckrodt has produced.

21 But, sir, I know you
22 reviewed a number of documents. You
23 reviewed about 150 out of the 1.6 million
24 that Mallinckrodt produced. So we

1 thought it would be helpful to put
2 together a chart to show you what year
3 those documents came from.

4 A. Okay.

5 Q. So go ahead and take a look
6 at this chart. Do you need any time?

7 A. I can see the chart.

8 Q. All right. So, sir, if you
9 look at the chart, it appears that you
10 reviewed four documents from 2018,
11 correct?

12 MR. BOGLE: Does this
13 include deposition exhibits?

14 MR. DAVISON: This includes
15 the documents that are listed on
16 his relied upon document.

17 MR. BOGLE: So it does
18 include deposition exhibits?

19 MR. DAVISON: I'm not sure
20 if it does include deposition
21 exhibits. I'm not going to
22 represent that it does.

23 MR. BOGLE: Okay.

24 THE WITNESS: So I see that

1 your chart says four, yes.

2 BY MR. DAVISON:

3 Q. Okay. Sir, in looking at
4 this chart, from 2013 to 2018, you
5 reviewed a total of 11 documents,
6 correct?

7 A. Those are the numbers that
8 you have, yes.

9 Q. Well, sitting here today do
10 you have any reason to doubt those
11 numbers?

12 MR. BOGLE: Object to form.

13 THE WITNESS: I think you
14 just raised one question. You
15 don't know whether it includes
16 deposition exhibits or not. So
17 I'm just going by the numbers that
18 are on your page.

19 BY MR. DAVISON:

20 Q. All right. Well, sir, can
21 you recall a single document that you
22 actually put a citation to in your report
23 from Mallinckrodt's SOM program post
24 2012?

1 A. Considering I have several
2 thousand footnotes, no, not off the top
3 of my head right here.

4 Q. Well, sir, if all of your
5 citations are prior to 2012, those are
6 the documents that you thought were most
7 important, right?

8 MR. BOGLE: Object to form.

9 THE WITNESS: Again, as I
10 said to you, you asked me if I
11 could recall. I told you I've got
12 thousands of footnotes. I can't
13 recall.

14 BY MR. DAVISON:

15 Q. Sir, what's the basis for
16 your statement that Mallinckrodt's
17 controlled substances compliance program
18 was not effective in 2016?

19 MR. BOGLE: Object to form.

20 THE WITNESS: Could you
21 restate the question for me,
22 please?

23 BY MR. DAVISON:

24 Q. Sir, what is the basis for

1 your statement that Mallinckrodt's
2 controlled substances compliance program
3 was not effective in 2016?

4 A. I'd have to go back and
5 review my report to be able to give you
6 an answer to that question.

7 Q. So you can't recall sitting
8 here today without going through your
9 report any basis for a claim that
10 Mallinckrodt's suspicious order
11 monitoring program was not effective in
12 2016?

13 A. I can't tell you without
14 reviewing my report in detail.

15 Q. Are you aware that
16 Mr. Rafalski said that he had no opinion
17 as to the effectiveness of Mallinckrodt's
18 suspicious order monitoring program post
19 2011?

20 A. I am not aware of what
21 Mr. Rafalski said about Mallinckrodt at
22 all.

23 Q. And, sir, if the only
24 documents you reviewed from 2000 -- from

1 post 2012 relating to Mallinckrodt's
2 controlled substances compliance program
3 were standard operating procedures, you'd
4 agree with me that that is not sufficient
5 for you to make a determination as to the
6 effectiveness of Mallinckrodt's
7 controlled substance compliance program,
8 right?

9 MR. BOGLE: Object to form.

10 THE WITNESS: Do you want to
11 restate the question?

12 MR. DAVISON: Can we read it
13 back?

14 (Whereupon, the court
15 reporter read back the requested
16 portion of testimony.)

17 THE WITNESS: If that was
18 the only documents that I
19 reviewed, I'm not sure how -- I'm
20 not sure what I can tell you on
21 that.

22 BY MR. DAVISON:

23 Q. Well, I think we agreed
24 earlier that looking at SOPs alone is not

1 consistent with your methodology for
2 evaluating the controlled substance
3 compliance program, correct?

4 A. Not a complete holistic
5 program, no. But you're assuming that
6 that's the only -- those are the only
7 documents that I looked at. Don't forget
8 that I looked at depositions, et cetera,
9 so...

10 Q. So I think your answer then,
11 if -- again, a hypothetical -- the only
12 documents that you looked at that were
13 post 2012 were standard operating
14 procedures, that would not be sufficient
15 for you to draw a conclusion as to the
16 effectiveness of Mallinckrodt's
17 controlled substance compliance program?

18 MR. BOGLE: Object to form.

19 THE WITNESS: Can you say it
20 again?

21 Brandon, can we take a
22 break? I need -- I need --

23 BY MR. DAVISON:

24 Q. There's a question pending.

1 MR. BOGLE: You can answer
2 the question and then we'll take a
3 break.

4 MR. DAVISON: Yeah, that's
5 fine.

6 THE WITNESS: I need to go
7 to the bathroom, actually.

8 BY MR. DAVISON:

9 Q. I just want an answer to my
10 question, and then we'll take a break.

11 A. Sure.

12 Q. So this is a hypothetical.
13 If the only documents that you looked at,
14 that were post 2012, that would not be
15 sufficient for you to draw a conclusion
16 as to the effectiveness of
17 Mallinckrodt's -- I'm going to strike
18 that and start over because reading it --

19 THE COURT REPORTER: You can
20 stop it. You can stop the
21 movement.

22 BY MR. DAVISON:

23 Q. Sir, if the only documents,
24 if the only Mallinckrodt documents that

1 you looked at post 2012 were standard
2 operating procedures, you would agree
3 with me that under your methodology, that
4 is not sufficient for you to draw a
5 conclusion as to the effectiveness of
6 Mallinckrodt's controlled substance
7 compliance program?

8 MR. BOGLE: Object to form.

9 THE WITNESS: I would say it
10 would be -- if that were the case,
11 I would say, it would be
12 sufficient to at least note that
13 there's a deficiency in the
14 program around written standards.

15 BY MR. DAVISON:

16 Q. And, sir, just one more
17 question. If you didn't write in your
18 report specific deficiencies relating to
19 standard operating procedures, are you
20 intending to offer an opinion as with
21 respect to those deficiencies?

22 A. I am not at this point
23 expecting to amend this report unless
24 there's new and available information for

1 me to work with.

2 Q. So sitting here today the
3 answer to that question is no?

4 MR. BOGLE: You can answer
5 that, and then we're taking a
6 break.

7 MR. DAVISON: Yeah.

8 THE WITNESS: As I said,
9 unless there's new available
10 information I need to consider, I
11 am not -- at this current point I
12 have no intention of amending the
13 report.

14 MR. BOGLE: All right.

15 MR. DAVISON: We can go off
16 the record.

17 THE VIDEOGRAPHER: Going off
18 the record at 4:19 p.m.

19 (Short break.)

20 THE VIDEOGRAPHER: Back on
21 the record at 4:34 p.m.

22 BY MR. DAVISON:

23 Q. All right. Dr. Whitelaw, we
24 were earlier talking about kind of the --

1 the time period for your review of
2 Mallinckrodt's anti-diversion compliance
3 program. Can you recall any documents
4 that you reviewed relating to
5 Mallinckrodt's anti-diversion compliance
6 program from prior to 2006?

7 A. You are asking me to recall
8 specific documents. I can't recall
9 specific documents. But you've obviously
10 charted it out.

11 One thing I wasn't clear,
12 when we broke, was, I did ask for
13 documents and did look at documents all
14 the way through 2018. And if you look at
15 the -- as you correctly noted, and we
16 were correctly having that discussion
17 right when the break took place, from
18 2012 onward, I haven't seen enough
19 documentation to be able to form an
20 opinion on the adequacy of an
21 anti-diversion program from Mallinckrodt
22 post 2012.

23 I would need to see
24 additional information. One of the

1 things that would be, obviously for me
2 would be particularly critical, and
3 something I know I asked for, there
4 weren't any documents to be had, would
5 have been audits.

6 Q. So, sir, I want to unpack
7 that a little bit.

8 A. Sure.

9 Q. Are you stating today that
10 you cannot offer an opinion as to the
11 adequacy of Mallinckrodt's anti-diversion
12 program post 2012?

13 A. That is what I'm saying. I
14 do not have enough information to offer
15 an opinion for or against.

16 Q. All right. So at trial,
17 you're not planning to offer an opinion
18 one way or the other regarding
19 Mallinckrodt's anti-diversion program
20 post 2012, correct?

21 A. Unless additional
22 information that is relevant to this
23 report became available and to be
24 considered, I have no present intention

1 of doing that.

2 Q. Okay. And if additional
3 information, you'd of course be required
4 to write a new report and we'd do this
5 all over again, correct?

6 MR. BOGLE: Object to form.

7 THE WITNESS: We'd certainly
8 be doing a supplement and having a
9 further conversation on a
10 supplement I'm sure.

11 BY MR. DAVISON:

12 Q. But you don't intend to
13 offer a supplement sitting here today?

14 MR. BOGLE: Object to form.

15 THE WITNESS: As I said, and
16 I've stated on the record right
17 now, no, I have no intention of
18 offering a supplement as we
19 described post 2012 on
20 Mallinckrodt's program without any
21 additional information.

22 BY MR. DAVISON:

23 Q. Thank you, sir.

24 So I want to -- I want to go

1 back to the beginning of the time period
2 for your -- your review.

3 Are you offering an opinion
4 as to the adequacy of Mallinckrodt's
5 controlled substance compliance program
6 from 1996 to 2006?

7 A. Again, I think we need to
8 look at the documents, where they fall
9 out. I'm looking at your program from
10 just before 2007, probably up through
11 2012 to be precise is where I had
12 documents. Although I asked for
13 documents going all the way back in time.

14 Q. So your report is offering
15 an opinion as to Mallinckrodt's
16 suspicious -- excuse me. Strike that.

17 Your report offers an
18 opinion as to the effectiveness of
19 Mallinckrodt's anti-diversion program
20 from 2007 to 2012, correct?

21 MR. BOGLE: Object to form.

22 THE WITNESS: I think to be
23 precise, it would probably be more
24 like 2008 to 2012. That's the

1 window in time that I have
2 documents, sufficient documents
3 for, to form an opinion.

4 BY MR. DAVISON:

5 Q. Thank you, sir.

6 And, sir, is that consistent
7 with your memory of the documents that
8 you reviewed?

9 A. Yes, I think it is
10 consistent with my -- the memory of the
11 documents. I'm not saying I didn't see
12 any documents. I'm saying I didn't see
13 the bulk of the documents fell out in
14 your bell curve.

15 Q. And, sir, just -- just so
16 we're clear, sitting here today, you do
17 not intend to offer an opinion as to the
18 effectiveness of Mallinckrodt's
19 anti-diversion compliance program from
20 1996 to 2007, correct?

21 MR. BOGLE: Object to form.

22 THE WITNESS: Again, I have
23 no -- unless I see some additional
24 information that warrants me to

1 revisit this issue, I do not have
2 a present intention of amending my
3 report as it stands today.

4 BY MR. DAVISON:

5 Q. Thank you, sir.

6 Sir, on Page 215 of your
7 report you reference an individual named
8 Victor Borelli. I'm looking at the third
9 paragraph. It starts: "Mr. Borelli
10 worked for Mallinckrodt from 2005 to
11 2012"?

12 A. Yes, as a matter of fact I
13 see the reference. I do.

14 Q. All right. And, sir, do you
15 also recall that in your report you
16 reference an individual from Mallinckrodt
17 named Hugh O'Neill?

18 A. Yes, sir. I actually do
19 remember referencing an individual,
20 Mr. Hugh O'Neill.

21 Q. You are aware that
22 Mr. O'Neill joined Mallinckrodt in 2013?

23 A. Yes, I'm aware that
24 Mr. O'Neill joined Mallinckrodt in 2013.

1 Q. So you have no reason to
2 believe that Mr. O'Neill and Mr. Borelli
3 ever overlapped at Mallinckrodt, correct?

4 A. That is correct. I have --
5 have no reason to believe that they ever
6 overlapped at Mallinckrodt.

7 Q. Sir, if you can turn to
8 Page 234 of your report.

9 A. Yes, I see it.

10 Q. You write -- I'm at the
11 third paragraph down.

12 A. Third paragraph down.

13 Q. It says "When Mallinckrodt."
14 Do you see that?

15 A. Yes.

16 Q. That's where it starts.

17 "When Mallinckrodt subsequently notified
18 distributors that it would not pay
19 chargeback on sales to multi-distributor
20 customers, Mallinckrodt failed to report
21 any of the orders that gave rise to
22 multi-distributor sales to the DEA as
23 suspicious."

24 All right, sir. Earlier

1 today, we talked a little bit briefly
2 about Mallinckrodt's chargeback
3 restriction program. Are you familiar
4 with Mallinckrodt's chargeback
5 restriction program?

6 A. In broad general terms, yes.
7 But would you care to refresh my
8 recollection of the conversation. Be
9 happy to. It's -- it's been 14 hours,
10 guys.

11 Q. Fair enough.

12 Mallinckrodt at times would
13 restrict chargeback payments --

14 A. Yes.

15 Q. -- with respect to certain
16 downstream pharmacies, do you recall
17 that?

18 A. Yes. Now I understand what
19 you are referring to. Thank you for
20 clarifying.

21 Q. Not a problem.

22 Did you analyze
23 Mallinckrodt's chargeback restriction
24 program as part of your anti-diversion

1 compliance review?

2 MR. BOGLE: Object to form.

3 THE WITNESS: I looked at --

4 I looked at how Mallinckrodt was

5 using chargeback data and

6 incorporating it into the SOMs

7 program as part of my review.

8 BY MR. DAVISON:

9 Q. And did you find flaws with
10 Mallinckrodt's chargeback restriction
11 program?

12 MR. BOGLE: Object to form.

13 THE WITNESS: I did not find

14 flaws with the restriction

15 program, per se. What I found a

16 flaw with was the presence of the

17 fact that Mallinckrodt had access

18 to this data for a long period of

19 time. And it wasn't until 2010

20 roughly that you started to use it

21 in the SOMs program. That was the

22 issue that I was raising with

23 chargebacks in particular.

24 BY MR. DAVISON:

1 Q. So -- so the flaw wasn't
2 with what Mallinckrodt did with it, but
3 when they started doing it. Is that
4 fair?

5 MR. BOGLE: Object to form.

6 THE WITNESS: Well, some of
7 it is a flaw of what Mallinckrodt
8 did or didn't do with it, but the
9 other part of the flaw is the fact
10 that there was data that
11 indicated, as my report indicates,
12 and I think we can go to the page
13 for example, on Page 235,
14 Mallinckrodt had visibility to
15 similar data that indicated that
16 you were working and dealing with
17 some pretty unsavory, shall we
18 say, distributors, and nothing was
19 done about it, even though you had
20 the presence of the data inhouse
21 until the DEA took action. So
22 that's another issue that I have
23 with how you used the data.

24 BY MR. DAVISON:

1 Q. Do you recall what
2 distributors you're referring to as
3 unsavory?

4 A. I believe the ones that I'm
5 referring to are on Page 235. So we're
6 looking at things like Harvard Drug
7 Group, Masters, Value Drug. I mean, we
8 could go through the entire list if you
9 would like.

10 Q. And, sir, are you aware that
11 Mallinckrodt audited Masters?

12 MR. BOGLE: Object to form.

13 THE WITNESS: I am aware
14 that you had a relationship with
15 Masters. I saw some documentation
16 surrounding it. But I didn't see
17 any indication that you -- that
18 showed a -- there was a deep dive
19 or a detailed review of Master. I
20 didn't see that.

21 BY MR. DAVISON:

22 Q. So you did not see a
23 detailed audit report from January of
24 2011 with respect to Masters

1 Pharmaceutical?

2 A. I don't rightly recall a
3 detailed audit report from Masters
4 Pharmaceuticals in 2011. I just don't.
5 I'm sorry.

6 Q. All right. That's fair. Do
7 you recall that Mallinckrodt stopped
8 shipping oxy 30 to Masters in the fall of
9 2010?

10 A. Again, my issue was that you
11 had data on hand, and it took the DEA to
12 take action against distributors for
13 Mallinckrodt to essentially stop.

14 Q. Well, sir, Masters DEA
15 didn't take action against until June of
16 2011. So are you aware that Mallinckrodt
17 stopped shipping oxy 30 for a period of
18 time starting in the fall of 2010?

19 A. Again, I have a vague
20 recollection of something similar to
21 that, but I can't point to a document if
22 that's what you're asking.

23 Q. That's fair enough. So when
24 you say that Mallinckrodt took no action,

1 that's not correct?

2 A. Took limited action.

3 MR. BOGLE: Object to form.

4 BY MR. DAVISON:

5 Q. In your view, Mallinckrodt
6 took limited action with respect to
7 Masters.

8 So you write here that,
9 "When Mallinckrodt subsequently notified
10 distributors that it would not pay
11 chargebacks on sales to multi-distributor
12 customers" --

13 A. Hold on, Counsel.

14 Q. I apologize.

15 A. Where are you, please.

16 Q. Fair enough.

17 A. You've lost me.

18 Q. We're still in that third
19 paragraph --

20 A. Third paragraph.

21 Q. -- of page 234?

22 A. Third paragraph, 234. Is
23 that where we are?

24 Q. Yeah, that's where we are.

1 A. Okay. Thank you.

2 Q. "When Mallinckrodt
3 subsequently notified distributors that
4 it would not pay chargebacks on sales to
5 multi-distributor customers, Mallinckrodt
6 failed to report any of the orders that
7 gave rise to multi-distributor sales to
8 the DEA as suspicious."

9 And you cite to Ginger
10 Collier's deposition for that
11 proposition. Do you know who Ginger
12 Collier is?

13 A. I don't recall her title off
14 the top of my head. But, actually, you
15 have my notes, right?

16 MR. BOGLE: I'll give it to
17 you.

18 THE WITNESS: Can I have my
19 notes?

20 Thank you.

21 BY MR. DAVISON:

22 Q. So just so you have the --
23 the question was just, do you know what
24 Ginger Collier's title is?

1 A. I do now.

2 Q. All right. You refreshed
3 your recollection with your notes?

4 A. I have. Director of
5 marketing.

6 Q. All right. I'm sorry. Go
7 ahead.

8 A. Director of marketing.

9 Q. Can we go ahead and mark
10 those notes?

11 MR. BOGLE: Sure.

12 MR. DAVISON: Thank you.

13 MR. BOGLE: You're welcome.

14 (Document marked for
15 identification as Exhibit
16 Whitelaw-24.)

17 BY MR. DAVISON:

18 Q. All right. So this is
19 Exhibit 24, which are copies of notes
20 that Dr. Whitelaw utilized in his
21 deposition. We'll make copies for
22 everyone after we get through.

23 A. Thank you.

24 Q. All right. So I'm going to

1 mark Exhibit 25.

2 A. Okay.

3 (Document marked for
4 identification as Exhibit
5 Whitelaw-25.)

6 BY MR. DAVISON:

7 Q. There you go.

8 A. Thank you.

9 Q. And so again, we were on
10 Page 234. And just so you know what
11 we're looking at, you had a statement
12 that Mallinckrodt notified distributors
13 that it would not pay chargebacks, but
14 Mallinckrodt failed to report any of the
15 orders that gave rise to
16 multi-distributor sales to the DEA as
17 suspicious.

18 Just let me know when you're
19 ready, sir.

20 A. Absolutely will let you know
21 when I'm ready. Thank you.

22 Q. Sir, do you remember
23 reviewing this document?

24 A. I remember seeing this

1 document, yes.

2 Q. Okay. And, sir, is this an
3 example of Mallinckrodt reporting
4 chargeback restrictions to the DEA under
5 21 C.F.R. 1301.74(b)?

6 A. It is an example of
7 notifying -- as I read the document, it's
8 a letter that they are sending to various
9 pharmacies with a copy to DEA of the
10 pharmacies that they are notifying that
11 they will no longer pay chargebacks for.

12 Q. So is this different from
13 what you referenced when you said,
14 "Mallinckrodt failed to report any of the
15 orders that gave rise to
16 multi-distributor sales to the DEA as
17 suspicious"?

18 A. Well, again, I would say it
19 is different on the grounds of what we're
20 talking about, is you're saying I'm
21 not -- I'm no longer -- at least as I
22 read it, this document is a form letter,
23 and the list of -- supposedly, I guess,
24 the list of addressees is Attachment 1,

1 that this letter was all going to. Going
2 to stop processing chargeback data.

3 But I don't see anywhere in
4 this letter where we talk about specific
5 orders. What I do is specific
6 distributors.

7 Q. So, sir, your statement here
8 is not that Mallinckrodt didn't report
9 the pharmacies to DEA, but rather that
10 Mallinckrodt is obligated to report each
11 individual chargeback to DEA?

12 MR. BOGLE: Object to form.

13 THE WITNESS: I didn't say
14 chargeback. If you notice my
15 report was careful to say orders.

16 BY MR. DAVISON:

17 Q. Well, so what orders are you
18 talking about?

19 MR. BOGLE: Object to form.

20 THE WITNESS: I'm talking
21 about the orders that went to
22 these pharmacies. What I'm saying
23 to you is you've given notice to
24 DEA you are cutting off these

1 various pharmacies. But you're
2 not giving any details behind
3 that.

4 BY MR. DAVISON:

5 Q. Sir, you're aware that
6 through ARCOS data, DEA has access to
7 every single order that a pharmacy places
8 from a distributor, correct?

9 A. I am aware of the ARCOS
10 dataset, yes.

11 Q. And so the issue you have
12 with what Mallinckrodt did here is that
13 while we provided them information on
14 pharmacies for which we had questions, we
15 didn't provide them with the data on the
16 orders which they already had, correct?

17 MR. BOGLE: Object to form.

18 THE WITNESS: I believe
19 that's what I noted in my report,
20 yes.

21 BY MR. DAVISON:

22 Q. Are you aware that in
23 November of 2010, Mallinckrodt requested
24 a meeting with DEA to present to DEA its

1 suspicious order monitoring program?

2 A. I recall a request for a
3 meeting. I can't point to a specific
4 document. Is there a specific place in
5 the report that we want to look at?

6 Q. No, I'll provide you with a
7 document. That will make it easier.

8 A. Great.

9 Q. Trying to make your life
10 easy.

11 A. I appreciate that.

12 Q. All right. Exhibit 26.

13 (Document marked for
14 identification as Exhibit
15 Whitelaw-26.)

16 THE WITNESS: Thank you so
17 very much.

18 MR. DAVISON: Just for the
19 people on the phone, this is Bates
20 number -- I'm sorry about that.
21 This is MNK-T1_ --

22 MR. BOGLE: Just -- I think
23 you gave me something new.

24 BY MR. DAVISON:

1 Q. MNK-T1_0000421974.

2 A. I see the document, yes.

3 Q. Sir, do you have a
4 recollection of reviewing this document
5 in preparation of your report?

6 A. I do recollect seeing this
7 document in the past, yes.

8 Q. Okay. And, sir, this looks
9 like notes from a meeting at DEA
10 St. Louis office, 11/01/10, correct?

11 A. That's what it appears to
12 be, yes. That's certainly what the title
13 of the document is.

14 Q. All right. You have no
15 reason to doubt that's what this document
16 is?

17 A. No, I don't have any reason
18 to doubt it.

19 Q. And under overview, it
20 states, "Mallinckrodt started the meeting
21 by indicating the appointment had been
22 requested to discuss Mallinckrodt's
23 enhancements to suspicious order
24 monitoring program, further to provide

1 DEA new statistical data that has been
2 gathered from sales chargeback monitoring
3 system."

4 Did I read that correctly?

5 A. I believe you did read that
6 correctly.

7 Q. All right. Sir, do you have
8 any reason to doubt that that's the
9 reason Mallinckrodt requested the
10 meeting?

11 MR. BOGLE: Object to form.

12 THE WITNESS: All I know is
13 what's written here in front of me
14 on the document. So I can't make
15 any other judgments than what I'm
16 seeing and reading on the
17 document.

18 BY MR. DAVISON:

19 Q. And that's true for -- for
20 every document you reviewed in this case,
21 correct?

22 A. I have to rely on the
23 documents if that's what you're asking,
24 yes, in -- in conjunction with the other

1 things I've looked at like deposition
2 testimony, et cetera.

3 So it's part of what I
4 relied on.

5 Q. Fair enough.

6 So this document is no
7 different from the other e-mails that are
8 cited in -- in your report. You rely on
9 that, the transcripts, everything we
10 discussed earlier with our methodology,
11 correct?

12 A. Correct.

13 Q. If you read down --
14 actually, let's -- let's move up. The
15 DEA attendees. One of the attendees is
16 Scott Collier, diversion program manager
17 (DPM) .

18 A. I see that.

19 Q. Do you see that?

20 A. Yes, I do, sir.

21 Q. Do you know who Scott
22 Collier is?

23 A. Not personally. I know who
24 he is as represented here.

1 Q. Do you know where in the DEA
2 hierarchy a diversion program manager is
3 compared to a diversion investigator?

4 A. Well, I would assume a
5 diversion program manager is higher than
6 a diversion investigator, but exactly how
7 many steps separate the two, I don't know
8 off the top of my head.

9 Q. All right. And if
10 Mr. Rafalski testified that the diversion
11 program manager is -- is two steps up
12 from a diversion investigator, you'd have
13 no reason to doubt that?

14 A. I would have no reason to
15 doubt that, no.

16 Q. And so if you go -- the
17 general feedback from DEA St. Louis, it
18 states, "The DPM commented that the
19 information Mallinckrodt presented was
20 the best suspicious order monitoring
21 process he has seen to date and what he
22 expected from Mallinckrodt as an industry
23 leader."

24 Did I read that correctly?

1 A. I do believe that you did
2 read that correctly.

3 Q. Sir, do you have any reason
4 to doubt that the diversion program
5 manager said that about Mallinckrodt's
6 suspicious order monitoring program in
7 2010?

8 MR. BOGLE: Object to form.

9 THE WITNESS: Could you
10 be -- could you restate the
11 question for me, please?

12 BY MR. DAVISON:

13 Q. Do you have any reason to
14 doubt that the diversion program manager
15 from DEA St. Louis stated that
16 "Mallinckrodt's suspicious order
17 monitoring process was the best that he
18 had seen to date and what he expected
19 from Mallinckrodt as an industry leader"?

20 MR. BOGLE: Same objection.

21 THE WITNESS: Again, all I
22 can comment on is this is a
23 document that appears -- which I'm
24 not even sure who created the

1 document, because it's not clear
2 from the document that I'm
3 reading -- but assuming it's a
4 Mallinckrodt employee who created
5 it, it is their recollection of
6 the meeting and I have no way of
7 knowing whether that's an accurate
8 statement by Mr. Collier or not.
9 All I know is what I'm reading
10 here.

11 BY MR. DAVISON:

12 Q. And you didn't make any
13 attempt to interview Mr. Collier about
14 it, correct?

15 A. No, sir, I did not interview
16 Mr. Collier.

17 Q. And the same is true with
18 respect to every other e-mail that you
19 cited in your report, you only have the
20 knowledge of what's on the document,
21 right?

22 MR. BOGLE: Object to form.

23 THE WITNESS: As I said, I
24 think we -- I think I was a little

1 clearer than that, but I only have
2 what's through knowledge of the
3 e-mails and the documents that I
4 see in front of me, as well as any
5 corresponding deposition
6 testimony, and any other documents
7 that, you know, are interplayed or
8 attachments or whatever else I
9 have to work with.

10 BY MR. DAVISON:

11 Q. And the depositions that you
12 reviewed relating to Mallinckrodt
13 employees, those were taken by
14 plaintiffs' counsel, correct?

15 A. Yes, Counsel, I believe they
16 were.

17 Q. Did plaintiffs' counsel ever
18 ask any of Mallinckrodt's employees about
19 this document?

20 A. Honestly I can't -- I've
21 reviewed quite a few depositions and I
22 don't honestly remember the details of
23 every deposition, so I can't tell you off
24 the top of my head, Counsel.

1 Q. So nothing stands out in
2 your mind as this being asked about in a
3 deposition, correct?

4 A. Nothing stands out that I
5 seem to remember.

6 Q. And so there's no deposition
7 testimony that would call into
8 question -- strike that.

9 Can you think of any
10 deposition testimony that you reviewed
11 that would call into question the
12 accuracy of the statement that the DPM
13 commented that "the information
14 Mallinckrodt presented was the best
15 suspicious order monitoring process he
16 has seen to date and what he expected
17 from Mallinckrodt as an industry leader"?

18 MR. BOGLE: Object to form.

19 THE WITNESS: Again,
20 Counsel, I don't recall anything
21 in a deposition transcript to that
22 effect.

23 BY MR. DAVISON:

24 Q. Now, if the DPM comment --

1 made that statement, do you think
2 Mallinckrodt could have relied upon it?

3 MR. BOGLE: Object to form.

4 THE WITNESS: Again, I think
5 it goes back to saying, if he made
6 the comment, he made the comment.
7 I don't know whether he made the
8 comment or he didn't. So I really
9 can't comment one way or the
10 other.

11 BY MR. DAVISON:

12 Q. And, sir, did you take this
13 document into account when making your
14 conclusions about the effectiveness of
15 Mallinckrodt's anti-diversion compliance
16 program in 2010?

17 A. Yes, I did.

18 Q. But you didn't cite this
19 document anywhere in your report,
20 correct?

21 A. No, sir, I did not.

22 Q. Do you think it's not
23 relevant what DEA says about a
24 registrant's suspicious order monitoring

1 program?

2 MR. BOGLE: Object to form.

3 Mischaracterizes the document, as
4 to speaking to DEA as a whole.

5 THE WITNESS: Could you
6 restate the question?

7 BY MR. DAVISON:

8 Q. Yeah. Do you think it's not
9 relevant what a diversion program manager
10 of DEA says about a registrant's
11 suspicious order monitoring program?

12 A. I didn't say that,
13 Counselor.

14 What I said was I can't tell
15 from this document, number one, whether
16 or not he actually made the comment or
17 not; and number two, in making that
18 comment, I have no idea what that -- if
19 there was any surrounding context is,
20 because I don't see here, and I don't
21 recall seeing what exactly was the
22 context of the conversation as well as
23 the presentation that was given. So I
24 don't know.

1 Q. So it's fair to say under
2 your methodology, you would not rely upon
3 meeting notes, correct?

4 MR. BOGLE: Object to form.
5 Misstates testimony.

6 THE WITNESS: I don't think
7 that that's what I'm saying. I'm
8 saying to you -- you're asking --
9 again, what exactly are you asking
10 me, Counsel?

11 BY MR. DAVISON:

12 Q. Do you think it's not
13 relevant what a diversion program manager
14 of DEA says about a registrant's
15 suspicious order monitoring program?

16 MR. BOGLE: Object to form.

17 THE WITNESS: I would say
18 that it is something to take into
19 account.

20 BY MR. DAVISON:

21 Q. So you took this into
22 account in coming to your conclusion that
23 Mallinckrodt's anti-diversion compliance
24 program in 2010 was not effective,

1 correct?

2 A. It was --

3 MR. BOGLE: Asked and
4 answered. You can answer again.

5 THE WITNESS: It was one of
6 many things I considered, but yes,
7 I took it into account.

8 BY MR. DAVISON:

9 Q. The next page states, "While
10 DEA cannot technically approve the
11 suspicious order monitoring program of
12 any registrant, the message from DEA was
13 that Mallinckrodt was on" -- "is on the
14 right track."

15 Did I read that correctly?

16 A. Yes, I believe you did read
17 the notes correctly.

18 Q. And you took this into
19 account in coming to your conclusion that
20 Mallinckrodt's anti-diversion compliance
21 program was not effective in 2010,
22 correct?

23 MR. BOGLE: Objection.

24 Asked and answered.

1 MR. DAVISON: It's a
2 different statement.

3 THE WITNESS: Same answer as
4 before.

5 BY MR. DAVISON:

6 Q. And you didn't cite to that
7 statement in your report either?

8 A. No, Counselor, I did not
9 cite to that statement in my report
10 either.

11 Q. Do you think this document
12 is important?

13 MR. BOGLE: Object to form.

14 THE WITNESS: Can you be a
15 lot more specific?

16 BY MR. DAVISON:

17 Q. Sure.

18 A. Because, I mean, that's a --

19 Q. Sure. We'll go there.

20 A. You can drive a truck
21 through that.

22 Q. You talked earlier about the
23 importance of looking at communications
24 with your regulator when you're analyzing

1 compliance?

2 A. Right. I did.

3 Q. So this is a memo of
4 communications with Mallinckrodt's
5 regulator -- excuse me -- regulator
6 relating to its controlled substances
7 compliance, correct?

8 MR. BOGLE: Object to form.

9 THE WITNESS: No, actually,
10 I don't see it as a communication
11 with Mallinckrodt's regulator.
12 What I see it is a recollection of
13 meeting notes between Mallinckrodt
14 and the DEA. I don't see this
15 as -- I don't see this, these
16 statements being made on official
17 DEA letterhead signed by the
18 diversion program manager. I
19 don't see anything official about
20 it.

21 So I -- other than the fact
22 that there was a meeting, and this
23 is the person's recollection of
24 the meeting that occurred, I'm

1 afraid I don't see this as an
2 official communication, if that's
3 where you're going.

4 BY MR. DAVISON:

5 Q. No, I didn't -- I didn't ask
6 that. But I just want to understand
7 this. So you haven't seen any notes from
8 DEA about this meeting that would
9 contradict this, correct?

10 MR. BOGLE: Object to form.

11 THE WITNESS: I haven't seen
12 any meeting notes period that
13 would give me a direction of
14 whether it occurred, didn't occur,
15 this was said, that was said. I
16 have nothing.

17 BY MR. DAVISON:

18 Q. And you haven't spoken to
19 anyone DEA -- at DEA about this meeting?

20 MR. BOGLE: Objection.

21 THE WITNESS: No, sir. I
22 have not spoken to anyone at DEA
23 about this particular meeting.

24 BY MR. DAVISON:

1 Q. So the only evidence that
2 you have about this meeting is this
3 document, correct?

4 MR. BOGLE: Object to form.

5 THE WITNESS: The only
6 evidence I have about this meeting
7 is what I've seen right here.

8 BY MR. DAVISON:

9 Q. All right. And although you
10 have nothing that contradicts this
11 evidence, you stated that because it's
12 meeting notes, you're not sure what
13 anyone said, correct?

14 MR. BOGLE: Object to form.

15 THE WITNESS: I'm saying to
16 you -- you're saying this is --
17 you have represented or at least
18 were representing, if I understood
19 you correctly, that this is what
20 DEA -- this was DEA's position to
21 Mallinckrodt at that time, and I'm
22 saying that I can't ascertain
23 that. I can tell you that this is
24 somebody's recollection of what

1 they thought was said in the
2 meeting by the DPM. Whether it
3 was or was not, I don't know.

4 BY MR. DAVISON:

5 Q. Sir, do you believe that
6 this was actually stated at the meeting?

7 MR. BOGLE: Objection.

8 Asked and answered.

9 THE WITNESS: I have told
10 you I don't have an opinion one
11 way or the other. I don't have
12 enough information to work from,
13 as to whether or not this is an
14 accurate -- this is what was said
15 in the meeting.

16 BY MR. DAVISON:

17 Q. So to have enough
18 information, when you have meeting notes,
19 you would need someone else's notes as
20 well to make that --

21 A. I'd need more corroboration.
22 It could be notes. It could be
23 testimony, it could be other things to
24 look at other than just a single --

1 Q. All right. So a single
2 piece of meeting notes is not sufficient
3 for you?

4 MR. BOGLE: Object to form.
5 That's a question?

6 BY MR. DAVISON:

7 Q. Yes. Let me rephrase.

8 MR. BOGLE: I just didn't
9 know if it was a question.

10 BY MR. DAVISON:

11 Q. A single set of meeting
12 notes without corroborating evidence is
13 not sufficient in your methodology for
14 reviewing a controlled substance
15 compliance program?

16 MR. BOGLE: Object to form.
17 Misstates his testimony.

18 THE WITNESS: Again, that's
19 not what I'm saying. I'm saying a
20 single piece of meeting notes made
21 by a registrant purporting to bind
22 the DEA to a policy statement, I
23 would need to see something more
24 official or more corroborating

1 evidence to say whether or not
2 that actually was said or not. I
3 don't know. I honestly don't
4 know.

5 BY MR. DAVISON:

6 Q. Is it fair to say that you
7 would take the same approach if you had a
8 single piece of meeting notes made by a
9 Detroit diversion investigator purporting
10 to bind the DEA to a policy statement?

11 MR. BOGLE: Object to form.

12 THE WITNESS: If I had a
13 single piece of meeting notes
14 purporting to state -- to state
15 DEA policy that that was what's
16 stated in the meeting, I would
17 still want to see more additional
18 evidence.

19 BY MR. DAVISON:

20 Q. Sir, based on your 30 years
21 of -- of experience, I assume you are
22 familiar with memorandum of agreements in
23 the pharmaceutical industry, correct?

24 A. Yes, I am.

1 Q. And these are essentially
2 agreements between a pharmaceutical
3 industry member or company and the
4 government, correct?

5 A. It's a broad
6 characterization, but I think it's a fair
7 characterization.

8 Q. And in those agreements,
9 let's use the term "manufacturer" to make
10 it a little -- little easier here.

11 A. Okay. That would be
12 helpful.

13 Q. A manufacturer could agree
14 in an MOA to do more than is required by
15 the statute, correct?

16 MR. BOGLE: Objection.
17 Vague and overbroad.

18 THE WITNESS: Could you be a
19 little more specific on where you
20 are trying to go? Because I'm not
21 sure of your question.

22 BY MR. DAVISON:

23 Q. Well, sure. So let's talk
24 about the CSA. Actually let's talk about

1 the suspicious ordering monitoring
2 regulation. Are you familiar with that,
3 we talked about it earlier?

4 A. I am familiar with that,
5 certainly.

6 Q. So a manufacturer could
7 agree in an MOA to do more than is
8 required by the suspicious order
9 monitoring regulation?

10 MR. BOGLE: Object to form.

11 THE WITNESS: Again, we're
12 talking about an incredibly broad
13 brush hypothetical. I would
14 assume --

15 BY MR. DAVISON:

16 Q. Sure. Let's -- let's --

17 A. -- in regards to any
18 standard, a manufacturer could decide to
19 go above and beyond, yes.

20 Q. And it could have entered
21 into a memorandum of agreement to do
22 that, correct?

23 MR. BOGLE: Object to form.

24 THE WITNESS: Assuming the

1 other side was willing to agree to
2 it, I would assume you could enter
3 into an agreement.

4 BY MR. DAVISON:

5 Q. So for example, if the CSA
6 requires that a manufacturer check the
7 locks on its vaults once per day, a
8 manufacturer could enter into an MOA that
9 they are going to check the locks on its
10 vault four times a day, correct?

11 A. Well, they certainly could
12 propose it. Whether or not that gets
13 agreed to, but --

14 Q. Fair enough. And if the
15 government agreed?

16 A. Yes, then you'd enter into
17 an agreement.

18 MR. BOGLE: Wait for him to
19 finish the question.

20 BY MR. DAVISON:

21 Q. And you'd agree with me,
22 sir, that that does not then mean that
23 the CSA requires everyone, all
24 manufacturers, to check the locks on

1 their vaults four times per day?

2 MR. BOGLE: Object to form.

3 THE WITNESS: I would say
4 the agreement -- again, it would
5 depend on how the agreement is
6 actually written.

7 But the agreement -- if the
8 agreement is only between two
9 parties I would say that we are
10 talking about the two parties.
11 But it does -- I think you need to
12 be careful here, Counsel, because
13 at least in my world, we look
14 at -- for example, let's take a
15 Corporate Integrity Agreement.
16 It's not binding, but it does
17 provide guidance as to where DEA's
18 thinking is.

19 And guidance as to what is
20 industry leading practice, so
21 other manufacturers should, in
22 fact, take note of it.

23 BY MR. DAVISON:

24 Q. So it's guidance, not an

1 obligation, correct?

2 MR. BOGLE: Object to form.

3 THE WITNESS: Between the

4 parties that are not -- the

5 parties of the memorandum, yes.

6 But it -- it's data that should be

7 factored in.

8 BY MR. DAVISON:

9 Q. Fair enough.

10 MR. DAVISON: Let's go ahead

11 and we'll take a quick break.

12 There's only ten minutes left. So

13 if we can go off the record.

14 THE VIDEOGRAPHER: Going off

15 the record. 5:11 p.m.

16 (Short break.)

17 THE VIDEOGRAPHER: We are

18 back on the record at 5:35 p.m.

19 BY MR. DAVISON:

20 Q. All right. Dr. Whitelaw, I

21 do have one more document to discuss

22 today.

23 A. Okay.

24 Q. I -- I think we talked, you

1 agreed kind of your opinion starts in
2 2007. So I want to start in 2007 with
3 the DEA guidance that was provided in a
4 December guidance level -- guidance
5 document.

6 The Bates number is USDEA
7 00005941. Sir, you can go ahead and take
8 a look at that document.

9 A. Okay.

10 Q. Sir, have you seen this
11 document before?

12 A. Yes, sir, I have actually.

13 Q. Have you seen this document
14 prior to your engagement in this
15 litigation?

16 A. I can't rightly recall
17 whether I've seen it prior to this
18 litigation, but -- so I can't -- I can't
19 answer that for you, sorry.

20 Q. And, sir, this is guidance
21 that's on a DEA letterhead, correct?

22 A. Yes, as it appears to be.

23 Q. And it says, "Letter is
24 being sent to every entity in the United

1 States registered with the Drug
2 Enforcement Administration, DEA, to
3 manufacture or distribute controlled
4 substances."

5 Do you see that?

6 A. I do see that, yes.

7 Q. Now sir, this is the DEA
8 guidance from December 20, 2007. Do you
9 see anything in this guidance that says a
10 manufacturer needs to look at chargeback
11 data?

12 A. I do not see anything in
13 this document where the word -- I do not
14 see the words "chargeback data" in this
15 discussion.

16 Q. Is there anything in this
17 document that you would interpret to
18 require a manufacturer to review
19 chargeback data?

20 A. Yes, actually I would.

21 Q. Where is that, sir?

22 A. I would look on Page 2. I
23 would look at the top of the page for
24 starters. And I would look at the

1 sentence that reads, "The determination
2 of whether an order is suspicious depends
3 not only on the ordering patterns of the
4 particular customer, but also on patterns
5 of the registrant's customer, based on
6 patterns throughout the relevant segment
7 of the regulated industry."

8 Q. And we talked earlier, a
9 manufacturer registrant's customer base
10 are distributors, correct?

11 A. We talked earlier that
12 that's their direct customer, yes.

13 Q. You're not claiming now that
14 Mallinckrodt's are selling directly to
15 individual pharmacies, correct?

16 A. I am not claiming that
17 Mallinckrodt is selling to individual
18 pharmacies.

19 Q. All right. And this states,
20 I think the -- the sentence you read
21 says, "The determination of whether an
22 order is suspicious depends not only on
23 the ordering patterns of the particular
24 customer, but also on the patterns of the

1 registrant's customer base and the
2 patterns throughout the relevant segment
3 of the regulated industry."

4 Sir, a chargeback is not an
5 order, correct?

6 MR. BOGLE: Object to form.

7 THE WITNESS: I would say a
8 chargeback is not an order.

9 BY MR. DAVISON:

10 Q. All right. And this does
11 not reference a chargeback, correct?

12 A. This does not reference the
13 chargeback.

14 Q. And, sir, is there anything
15 in this letter that explicitly states
16 that a manufacturer must know its
17 customer's customer?

18 A. I do not see the words "know
19 your customer's customer" in this
20 particular letter that you are showing
21 me.

22 Q. And there's nothing in here
23 stating that a manufacturer needs to
24 monitor pharmacies that order from

1 distributors, correct?

2 MR. BOGLE: Object to form.

3 THE WITNESS: Could you
4 restate the question for me
5 please, Counsel?

6 BY MR. DAVISON:

7 Q. And there's nothing in here
8 stating that a manufacturer needs to
9 monitor pharmacies that order from
10 distributors, correct?

11 MR. BOGLE: Object to form.

12 THE WITNESS: I do not see
13 those words in this letter that --
14 in this document that you're
15 showing me right at this moment.

16 BY MR. DAVISON:

17 Q. Sir, would you agree that
18 the focus of this letter is on monitoring
19 orders from a registrant's customer?

20 MR. BOGLE: Object to form.

21 THE WITNESS: No, Counselor,
22 I would disagree with that. I
23 think it's on anti-diversion in
24 general and suspicious -- and

1 suspicious order monitoring as
2 well, but I believe we are talking
3 about -- because as he starts out
4 in his letter on the first full
5 paragraph -- sorry, second full
6 paragraph on the first page, he
7 talks about the controlled
8 substances statute and where we
9 were talking about that, those
10 favorite words of yours, of the
11 anti-diversion program, having an
12 effective anti-diversion program.

13 BY MR. DAVISON:

14 Q. All right. So I think your
15 statement was that this covers
16 anti-diversion in general as well as
17 suspicious order monitoring.

18 Focusing on suspicious
19 ordering monitoring, would you agree that
20 the focus of this letter with respect to
21 suspicious order monitoring is on
22 monitoring a registrant's direct
23 customers?

24 MR. BOGLE: Object to form.

1 THE WITNESS: No, Counselor.
2 I just see the term "customer." I
3 don't see customers, indirect
4 customers. I just see customers.
5 So I'm sorry. I don't.

6 BY MR. DAVISON:

7 Q. I think you said already
8 that for a manufacturer, its customers
9 are distributors, correct?

10 MR. BOGLE: Object to form.

11 THE WITNESS: In most cases,
12 yes, that's what I did say.

13 BY MR. DAVISON:

14 Q. All right. So you're not
15 saying that manufacturers are selling to
16 individual pharmacies?

17 MR. BOGLE: Object to form.

18 THE WITNESS: I was saying
19 to you that I didn't --
20 Mallinckrodt wasn't selling to
21 individual pharmacies that I was
22 aware of.

23 BY MR. DAVISON:

24 Q. Fair enough. That's the

1 only one that you reviewed, correct?

2 A. Correct.

3 Q. All right. Are you aware of
4 any official DEA guidance after this
5 December 20, 2007 -- excuse me. Strike
6 that.

7 Are you aware of any
8 official DEA guidance after this
9 December 20, 2007, letter but before
10 Mallinckrodt started monitoring
11 chargebacks that stated a manufacturer
12 needs to know its customer's customers?

13 MR. BOGLE: Object to form.

14 THE WITNESS: Counselor, let
15 me go through my report.

16 BY MR. DAVISON:

17 Q. So sitting here today,
18 without going through your report, you're
19 not aware of any DEA guidance that stated
20 that?

21 MR. BOGLE: Object to form.

22 THE WITNESS: Counsel, as I
23 said, I need to look at my report
24 if you want me to answer the

1 question.

2 BY MR. DAVISON:

3 Q. So you can't answer the
4 question without looking at your report?

5 MR. BOGLE: Object to form.

6 THE WITNESS: I want to be
7 sure on what I'm answering to you,
8 so I would like to look at my
9 report.

10 (Document marked for
11 identification as Exhibit
12 Whitelaw-27.)

13 BY MR. DAVISON:

14 Q. Okay. Sir, are you aware of
15 DEA ever sending a letter like this to
16 manufacturers telling them that they need
17 to monitor chargeback data?

18 MR. BOGLE: Object to form.

19 THE WITNESS: Could you ask
20 that question again, please.

21 BY MR. DAVISON:

22 Q. Yeah, no problem. Are you
23 aware of DEA ever sending a letter like
24 Exhibit 27, telling manufacturers that

1 they're obligated to monitor chargeback
2 data?

3 MR. BOGLE: Object to form.

4 THE WITNESS: Well, I think
5 I'm going to have to break your --
6 break your question down into two
7 parts. I'm aware of the fact that
8 letters like this were sent to
9 manufacturers. I don't recall in
10 the letters that I have seen,
11 seeing anything referencing --
12 seeing the words "chargeback
13 data."

14 BY MR. DAVISON:

15 Q. And, sir, earlier we talked
16 about how corporate integrity agreements
17 and MOAs are guidance, correct?

18 MR. BOGLE: Object to form.

19 THE WITNESS: Well --

20 BY MR. DAVISON:

21 Q. Or strike that.

22 Earlier today we talked
23 about how MOAs can be used by others in
24 the industry that have not signed the MOA

1 as guidance, correct?

2 A. Yes, we did talk about that.

3 Q. And this letter here, would
4 you agree that this is a piece of
5 guidance provided to industry?

6 A. I would agree that it looks
7 like an official piece of guidance
8 provided to industry, yes.

9 Q. And guidance doesn't
10 necessarily create an obligation,
11 correct?

12 MR. BOGLE: Object to form.

13 THE WITNESS: When you say
14 "obligation," could you be a bit
15 more specific?

16 BY MR. DAVISON:

17 Q. Yeah. Guidance doesn't
18 necessarily create a new obligation under
19 a statute?

20 MR. BOGLE: Object to form.

21 THE WITNESS: I believe
22 guidance expounds on existing
23 statutes and regulations and
24 provides additional clarity.

1 MR. BOGLE: We are at
2 14 hours.

3 MR. DAVISON: All right. I
4 see my time is up. I know that a
5 number of individuals did not have
6 enough time to question the
7 witness, given the multitude of
8 opinions, the length of the
9 report, and the witness's answers.
10 So we reserve the right to reopen
11 the deposition as necessary. Off
12 the record.

13 THE VIDEOGRAPHER: Going off
14 the record 5:46 p.m.

15 (Brief pause.)

16 THE VIDEOGRAPHER: Back on
17 the record at 5:48 p.m.

18 - - -

19 EXAMINATION

20 - - -

21 BY MR. BOGLE:

22 Q. Hi, Dr. Whitelaw. I've got
23 a -- my name is Brandon Bogle. I've got
24 a few follow-up questions for you. Can

1 you go back to Exhibit 26 for me, please?

2 A. Yes, sir. I have it in
3 front of me.

4 Q. Okay. Do you recall being
5 asked some questions about this document?

6 A. Yes, I do.

7 Q. Okay. And do you recall
8 specifically being asked some questions
9 about statements from an individual from
10 DEA, Scott Collier?

11 A. Yes, I do recall that.

12 Q. Okay. And this document,
13 does it indicate what information was
14 presented by Mallinckrodt at this meeting
15 to Scott Collier?

16 A. No, sir, it does not.

17 Q. Okay. And could you go
18 specifically to Page 209 of your report
19 for me, please?

20 A. Yes, sir. I'm there.

21 Q. Okay. And if you look at
22 the last paragraph here on this page you
23 note, "In 2017, Mallinckrodt entered into
24 an agreement with the DEA to resolve the

1 agency's ongoing investigations and
2 settled allegations made by the DEA that
3 the company, prior to 2012, failed to
4 maintain and operate an effective
5 anti-diversion program."

6 Did I read that correctly?

7 A. Yes, sir, I think you did.

8 Q. And you see there, you cite
9 to a Footnote 1238?

10 A. I do.

11 Q. Okay. And in Footnote 1238
12 if you see in the last parenthetical, you
13 note, "The investigation related to the
14 settlement" -- the formal investigation
15 DEA -- "The formal DEA investigation
16 began in September of 2011."

17 Do you see that?

18 A. Yes, sir, I do.

19 Q. Okay. The information that
20 you discussed related to the 2017
21 settlement agreement and the time period
22 in which the investigation related to it
23 occurred, how does that impact the
24 statements for -- the alleged statements

1 from Scott Collier in Exhibit 26 in your
2 view?

3 MR. DAVISON: Objection to
4 form.

5 THE WITNESS: Basically what
6 this says to me is that this was
7 not -- his position, assuming this
8 was, in fact, what he said at that
9 time in that report and at that
10 statement in that meeting is not
11 consistent with DEA's position
12 overall, as evidenced by the fact
13 that they commenced an
14 investigation and subsequently
15 Mallinckrodt settled with the DEA
16 in 2017 for controlled substances
17 issues and anti-diversion issues.

18 BY MR. BOGLE:

19 Q. Okay. Do you recall earlier
20 in your discussion with Mallinckrodt's
21 counsel, providing testimony to the
22 effect that you were not expressing any
23 opinions about Mallinckrodt's suspicious
24 order monitoring program prior to 2008?

1 A. Yes, I do recall that.

2 Q. Okay. Could I direct you to
3 Page 219 of your report please?

4 A. Absolutely. I am there.

5 Q. And if you see the first
6 sentence on this page it says, "Prior to
7 2008, Mallinckrodt's anti-diversion
8 program was marked by an absence of
9 formal written standards."

10 Do you see that statement?

11 A. Yes, I do.

12 Q. Is that a statement that you
13 wrote in this report?

14 A. Yes, it's a statement I
15 wrote in this report.

16 Q. Do you still believe that
17 statement to be true today?

18 A. Yes, I still believe that
19 statement to be true today.

20 Q. Okay. And if we can now go
21 to Page 216 of your report.

22 If you see under 14.4.2 A,
23 the first sentence there states, "Prior
24 to March 2008, there is scant evidence

1 that Mallinckrodt had a formally
2 designated SOM team."

3 Do you see that?

4 A. Yes, I do.

5 Q. Do you write that statement
6 in your report?

7 A. Yes.

8 Q. Do you still hold that
9 opinion today?

10 A. Yes, I still believe that's
11 correct.

12 Q. So given these two opinions,
13 Number 1 that prior to March 2008 there
14 is scant evidence that Mallinckrodt had a
15 formally designated SOM team, and that
16 prior to 2008 there was an absence of
17 formal written standards surrounding
18 anti-diversion, what does that say in
19 your mind concerning whether you actually
20 are offering opinions that there were
21 defects in Mallinckrodt's anti-diversion
22 program prior to 2008?

23 MR. DAVISON: Objection to
24 form.

1 MS. CASTLES: Object to
2 form.

3 MS. MONAGHAN: Object to
4 form.

5 THE WITNESS: I would offer
6 the opinion that, in fact, it
7 is -- there are defects in
8 Mallinckrodt's program prior to
9 2008 based on this evidence and
10 the fact that there -- there is
11 nothing to indicate there -- the
12 existence of that formal program.

13 BY MR. BOGLE:

14 Q. And the last thing I want to
15 discuss with you, if you can go to
16 Page 128 of your report.

17 A. All right. Flipping there.
18 Okay. Got it.

19 Q. Okay. If we can go to the
20 third paragraph here.

21 A. Okay.

22 Q. You state, "But they" -- and
23 the "they" here you are talking about
24 ABC, correct?

1 A. That is correct.

2 Q. "But they worked to
3 configure a program that only addressed
4 the bare minimums and did not interfere
5 with ABC's pursuit of ever increasing
6 revenues."

7 Do you see that statement?

8 A. Yes, sir, I do see the
9 statement.

10 Q. Do you recall being asked
11 some questions earlier today about this
12 statement concerning ABC doing the bare
13 minimums in this regard?

14 A. Yes, I do recall having a
15 conversation on that.

16 Q. Okay. And -- and in this
17 report and your prior testimony today on
18 that issue, what were you intending to
19 convey about ABC doing the bare minimum
20 in this context?

21 MS. CASTLES: Object to
22 form.

23 MR. HYNES: Object to form.

24 MR. MELTON: Object to form.

1 MS. MONAGHAN: Object to
2 form.

3 THE WITNESS: What I was
4 trying to convey, and apparently,
5 again, I don't think I was very
6 clear. What I was trying to
7 convey, when I said bare minimums,
8 I mean just the bare minimum, in
9 other words, just what's necessary
10 to -- to avoid an enforcement
11 action or other regulatory
12 sanctions from DEA.

13 BY MR. BOGLE:

14 Q. During the review period for
15 ABC specifically, what is your opinion
16 concerning whether ABC acted as a
17 responsible and reasonable distributor as
18 to their SOMs and anti-diversion program?

19 UNIDENTIFIED LAWYER:

20 Objection to form.

21 THE WITNESS: I would argue
22 that they were not reasonable.

23 BY MR. BOGLE:

24 Q. Is that an opinion you still

1 hold today?

2 A. That is an opinion I still
3 hold today.

4 MR. BOGLE: No further
5 questions.

6 MR. DAVISON: Go off.

7 THE VIDEOGRAPHER: Going off
8 the record, 5:54 p.m.

9 (Brief recess.)

10 THE VIDEOGRAPHER: Back on
11 record, 5:58 p.m.

12 MR. DAVISON: Dr. Whitelaw,
13 thank you for your time today. I
14 personally have no further
15 questions.

16 But again as I mentioned
17 earlier, reserve the rights for
18 the defendants that did not have
19 time and for Mallinckrodt because
20 we did not get to cover all -- all
21 of your opinions.

22 MR. BOGLE: Is anybody else
23 asking? Or is that for everybody?

24 MR. DAVISON: Everybody,

1 correct.

2 THE VIDEOGRAPHER: This ends
3 today's deposition. We're going
4 off the record at 5:58 p.m.

5 (Excused.)

6 (Deposition concluded at
7 approximately 5:58 p.m.)

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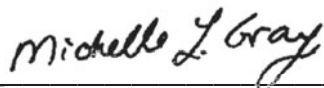
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1
2 CERTIFICATE
3
4

5 I HEREBY CERTIFY that the
6 witness was duly sworn by me and that the
7 deposition is a true record of the
8 testimony given by the witness.

9 It was requested before
10 completion of the deposition that the
11 witness, DR. SETH B. WHITELOW, have the
12 opportunity to read and sign the
13 deposition transcript.

14
15 

16 MICHELLE L. GRAY,
17 A Registered Professional
18 Reporter, Certified Shorthand
19 Reporter, Certified Realtime
20 Reporter and Notary Public
21 Dated: May 20, 2019
22
23
24

25 (The foregoing certification
26 of this transcript does not apply to any
27 reproduction of the same by any means,
28 unless under the direct control and/or
29 supervision of the certifying reporter.)
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32

1 INSTRUCTIONS TO WITNESS

2
3 Please read your deposition
4 over carefully and make any necessary
5 corrections. You should state the reason
6 in the appropriate space on the errata
7 sheet for any corrections that are made.

8 After doing so, please sign
9 the errata sheet and date it.

10 You are signing same subject
11 to the changes you have noted on the
12 errata sheet, which will be attached to
13 your deposition.

14 It is imperative that you
15 return the original errata sheet to the
16 deposing attorney within thirty (30) days
17 of receipt of the deposition transcript
18 by you. If you fail to do so, the
19 deposition transcript may be deemed to be
20 accurate and may be used in court.

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4 PAGE LINE CHANGE

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2 ACKNOWLEDGMENT OF DEPONENT
3

4 I, _____, do
5 hereby certify that I have read the
6 foregoing pages, 524 - 1007, and that the
7 same is a correct transcription of the
8 answers given by me to the questions
9 therein propounded, except for the
10 corrections or changes in form or
11 substance, if any, noted in the attached
12 Errata Sheet.
13
14
15

16 _____
17 DR. SETH B. WHITELAW

DATE

18
19 Subscribed and sworn
20 to before me this

_____ day of _____, 20____.

21 My commission expires: _____
22 _____

23 Notary Public
24

	LAWYER'S NOTES		
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